**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

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**FORM 10-K**

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**(Mark One)**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the Fiscal Year Ended December 31, 2021**
**or**
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Commission File Number: 001-36817**

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**AVINGER, INC.**
(Exact name of registrant as specified in its charter)

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| **Delaware** | **20-8873453** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |

**400 Chesapeake Drive**
**Redwood City, California 94063**
(Address of principal executive offices and zip code)
**(650) 241-7900**
(Telephone number, including area code)

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Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class:** | **Trading Symbol(s):** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, par value $0.001 per share | AVGR | The Nasdaq Capital Market |

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Accelerated filer ☐
Non-accelerated filer ☒
Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of a share of the registrant’s common stock on June 30, 2021, the last business day of the registrant’s most recently completed second fiscal quarter, as reported by the Nasdaq Capital Market on such date, was approximately $116.8 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 18, 2022, the number of outstanding shares of the registrant’s common stock, par value $0.001 per share, was 5,428,770.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

**AVINGER, INC.**
**ANNUAL REPORT ON FORM 10-K**
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2021**
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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the outcome of and expectations regarding our current clinical studies, and any additional clinical studies we initiate;
- our plans to modify our current products, or develop new products, to address additional indications;
- our ability to obtain additional financing through future equity or debt financings;
- the expected timing of 510(k) clearances by the FDA for enhanced versions of Pantheris, Ocelot and Lightbox;
- the expected timing of 510(k) submission to the FDA, and associated marketing clearances by the FDA, for additional versions of Pantheris, Ocelot and Lightbox;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;
- our ability to regain and remain in compliance with the listing requirements of the Nasdaq Capital Market;
- our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- our expectations regarding revenue, cost of revenue, gross margins, and expenses, including research and development and selling, general and administrative expenses;
- our expectations of qualitative and quantitative effects of COVID-19 to the extent discussed, as well as any expectations of recovery from or forward looking short-term or long-term implications thereof;
- the effects of the COVID-19 pandemic on our business and results of operations;
- our ability to identify and develop new and planned products and acquire new products;
- our financial performance;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business, both in the United States and internationally; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in Part I, Item 1A under the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. We urge you to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the United States Securities and Exchange Commission ("SEC") as exhibits to the Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

## PART I

### ITEM 1. BUSINESS

**Overview**

We are a commercial-stage medical device company that designs, manufactures and sells real-time image-guided, minimally invasive catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular real-time image-guided system available in this market.

We design, manufacture, and sell a suite of products in the United States and select international markets. We are located in Redwood City, California. Our current proprietary image-guided Lumivascular platform includes the Lightbox real-time imaging console, the Ocelot family of catheters, which are image-guided catheters designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and the Pantheris family of catheters, our image-guided atherectomy family of catheters designed to allow physicians to precisely remove arterial plaque in PAD patients.

We received CE Marking for our original Ocelot product in September 2011 and received from the U.S. Food and Drug Administration, or FDA, 510(k) clearance in November 2012. We received 510(k) clearance from the FDA for commercialization of Pantheris in October 2015. We received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select European countries promptly thereafter. In May 2018, we received 510(k) clearance from the FDA for our current next-generation version of Pantheris. In April 2019, we received 510(k) clearance from the FDA for our Pantheris SV, a version of Pantheris targeting smaller vessels, and commenced sales in July 2019. In September 2020, we received 510(k) clearance of Tigereye, a next-generation CTO crossing system utilizing Avinger's proprietary image-guided technology platform. Tigereye is a product line extension of Avinger's Ocelot family of image-guided CTO crossing catheters. In January 2022, we received 510(k) clearance from the FDA for our Lightbox 3 imaging console, a version of our Lightbox presenting significant reductions in size, weight and cost in comparison to the incumbent version.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain, and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments for PAD include stenting, angioplasty, and atherectomy, which is the use of a catheter-based device for the removal of plaque. These treatments all have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which is referred to as the external elastic lamina, or EEL.

We believe our Lumivascular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment through the use of optical coherence tomography, or OCT, a high resolution, light-based, radiation-free imaging technology. Our Lumivascular platform provides physicians with real-time OCT images from the inside of an artery, and we believe Ocelot and Pantheris are the first and only products in the market to offer intravascular visualization during CTO crossing and atherectomy, respectively. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our Lumivascular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding damage to healthy portions of the artery.

During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support our August 2015 510(k) submission to the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and efficacy endpoints. We believe the data from VISION allows us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the external elastic lamina, which is the membrane between the outermost layers of the artery, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. Although the original VISION study protocol was not designed to follow patients beyond six months, we worked with 18 of the VISION sites to re-solicit consent from previous clinical trial patients in order for them to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the remaining patients from participating sites was completed in May 2017, and we released the final 12- and 24-month results for a total of 89 patients in July 2017.

During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a submission to the FDA to expand the indication for our Pantheris atherectomy device to include in-stent restenosis. Patient enrollment began in October 2017 and was completed in July 2021. Patient outcomes were evaluated at thirty days, six months and one year following treatment. In November 2021, we received 510(k) clearance from the FDA for a new clinical indication for treating in-stent restenosis with Pantheris using the data collected and analyzed from INSIGHT. We expect this will expand our addressable market for Pantheris to include a high-incidence disease state for which there are few available indicated treatment options.

We focus our direct sales force, marketing efforts and promotional activities on interventional cardiologists, vascular surgeons and interventional radiologists. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. Although our sales and marketing efforts are directed at these physicians since they are the primary users of our technology, we consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products. We are designing additional future products to be compatible with our Lumivascular platform, which we expect to enhance the value proposition for hospitals to invest in our technology. Pantheris qualifies for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our products.

We have assembled a team with extensive medical device development and commercialization experience in both start-up and large, multi-national medical device companies. We assemble all of our products at our manufacturing facility but certain critical processes, such as coating and sterilization, are performed by outside vendors. We expect our current manufacturing facility in California, will be sufficient through at least 2022. We generated revenues of $9.1 million in 2019, $8.8 million in 2020 and $10.1 million in 2021. The decline revenue in 2020 was primarily due to the adverse effects of COVID-19 on our customers as hospitals deferred elective procedures.

**Our Products**

Our current products include our Lightbox imaging console and our various catheters used in PAD treatment. All of our revenues are currently derived from sales of our various PAD catheters and Lightbox imaging console and related services in the United States and select international markets. Each of our current products is, and our future products will be, designed to address significant unmet clinical needs in the treatment of vascular disease.

**LUMIVASCULAR PRODUCTS**

| Name | Clinical Indication | Size (Length, Diameter) | Regulatory Status | Original Clearance Date |
|---|---|---|---|---|
| **PRODUCTS** | | | | |
| Lightbox (1) | OCT Imaging | N/A | FDA Cleared<br>CE Marking | November 2012<br>September 2011 |
| Lightbox 3 (2) | OCT Imaging | N/A | FDA Cleared | January 2022 |
| Pantheris SV (small vessel) (3) | Atherectomy | 140cm, 6F | FDA Cleared<br>CE Marking | April 2019<br>October 2018 |
| Pantheris (next-generation) (4) | Atherectomy | 110cm, 7F | FDA Cleared<br>CE Marking | May 2018<br>December 2017 |
| Ocelot (5) | CTO Crossing | 110cm, 6F | FDA Cleared<br>CE Marking | November 2012<br>September 2011 |
| Ocelot MVRX (5) | CTO Crossing | 110cm, 6F | FDA Cleared | December 2012 |
| Ocelot PIXL (5) | CTO Crossing | 135cm, 5F | FDA Cleared<br>CE Marking | December 2012<br>October 2012 |
| Tigereye (5) | CTO Crossing | 140cm, 5F | FDA Cleared<br>CE Marking | September 2020<br>December 2019 |
| **PIPELINE PRODUCTS** | | | | |
| Tigereye ST (spinning tip) | CTO Crossing | | | |
| Pantheris LV (large vessel) | Atherectomy | | | |

(1) Lightbox is cleared for use with compatible Avinger products.

(2) The Lightbox 3 incorporates advanced features, including an advanced solid-state laser for enhanced high-definition OCT imaging, a more powerful computing platform, and a redesigned software system with a highly intuitive user interface that emphasizes efficiency and ease-of-use, intended to deliver advancements in imaging and portability. We initiated a limited launch of Lightbox 3 in the United States in the first quarter of 2022 and expect to expand to full commercial availability shortly thereafter.

(3) The Pantheris SV system is intended to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature with a reference diameter of 2.0 mm to 4.0 mm, using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen, wall structures and vessel morphologies. The Pantheris SV system is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

(4) The Pantheris system is intended to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature with a reference diameter of 3.0 mm to 7.0 mm, using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen, wall structures and vessel morphologies. The Pantheris system is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

(5) The Ocelot system is intended to facilitate the intra-luminal placement of conventional guidewires beyond stenotic lesions including subtotal and chronic total occlusions in the peripheral vasculature prior to further percutaneous interventions using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy and provides images of vessel lumen, plaques and wall structures. The Ocelot system is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature.

***Lumivascular Platform Overview***

Our Lumivascular platform integrates OCT (optical coherence tomography) visualization with interventional catheters and is the industry's only system that provides real-time intravascular imaging simultaneously with treatment in PAD procedures. Our Lumivascular platform consists of a capital component, Lightbox, and a variety of disposable catheter products, including the Ocelot and Pantheris family of catheters.

***Lightbox***

Lightbox, including its subsequent versions, is our proprietary video imaging console, which enables the use of Lumivascular catheters during PAD procedures. The console contains an optical transceiver that transmits light into the artery through an optical fiber and displays a cross-sectional image of the vessel to the physician on a high-definition monitor during the procedure.

Lightbox displays a cross-sectional view of the vessel, which provides physicians with detailed information about the orientation of the catheter and the surrounding artery and plaque. Layered structures represent relatively healthy portions of the artery and non-layered structures represent the plaque that is blocking blood flow in the artery. Navigational markers allow the physician to orient the catheter toward the treatment area, helping to avoid damage to the healthy arterial structures during a procedure. Lightbox received FDA 510(k) clearance in November 2012 and CE Marking in Europe in September 2011.

In January 2022, we received 510(k) clearance from the FDA for our next generation Lightbox 3 imaging console, the Lightbox 3, a version of our Lightbox that delivers important advancements in imaging, portability and capability in comparison to the incumbent version. Lightbox 3 incorporates advanced features, including an advanced solid-state laser for enhanced high-definition OCT imaging, a more powerful computing platform, and a redesigned software system with a highly intuitive user interface that emphasizes efficiency and ease-of-use. We initiated a limited launch of Lightbox 3 in the United States in the first quarter of 2022 and expect to expand to full commercial availability shortly thereafter.

***Pantheris***

We believe Pantheris is the first atherectomy catheter to incorporate real-time OCT intravascular video imaging. Pantheris may be used alone or following a CTO crossing procedure using Ocelot or other products. Pantheris is a single-use product and provides physicians with the ability to see a cross-sectional view of the peripheral artery to guide the removal of blockages throughout the procedure. The Pantheris device restores blood flow by shaving strips of plaque using a high-speed directional cutting mechanism that enables physicians to specifically target the portion of the artery where the plaque resides while minimizing disruption to healthy arterial structures. The excised plaque is deposited, collected and contained into the nosecone of the Pantheris device and removed from the artery within the device.

In October 2015, we received 510(k) clearance from the FDA for commercialization of Pantheris. We made modifications to Pantheris after the completion of the VISION trial and commenced sales in the United States and select international markets following receipt of FDA approval for this initial version of Pantheris in March 2016. We first received CE Marking for Pantheris in June 2015. We received CE Marking in December 2017 and 510(k) clearance in May 2018 for a next-generation version of Pantheris, which includes new features and design improvements to the handle, shaft, balloon and nosecone of the device. The next-generation Pantheris atherectomy device is currently available for commercial sale in the United States and select international markets. All previous versions of Pantheris have been discontinued.

We also developed a line extension of our Pantheris image-guided atherectomy platform, Pantheris SV (Small Vessel), a lower profile version of Pantheris. The Pantheris SV has a smaller diameter and longer length and is designed for use in smaller vessels 2.0 to 4.0 millimeters in diameter. We received CE Marking in October 2018 and 510(k) clearance in April 2019 for this product and commenced sales in the United States in July 2019.

***Ocelot and Tigereye***

Ocelot is the first CTO crossing catheter to incorporate real-time OCT video imaging, which allows physicians to see the inside of a peripheral artery during a CTO crossing procedure. Physicians have traditionally relied solely on fluoroscopy and tactile feedback to guide catheters through complicated blockages. Ocelot allows physicians to accurately navigate through CTOs by utilizing the OCT images to precisely guide the device through the arterial blockage, while minimizing disruption to the healthy arterial structures. A successful CTO crossing and placement of a guidewire allows the physician to subsequently treat the vessel with a minimally invasive therapeutic device. We received CE Marking for Ocelot in September 2011 and received FDA 510(k) clearance in November 2012.

We also offer Ocelot PIXL, a lower profile CTO crossing device for below-the-knee arteries and Ocelot MVRX, which offers a different tip design for peripheral arteries above-the-knee. We received CE Marking for Ocelot PIXL in October 2012 and received FDA 510(k) clearance in December 2012. We received FDA 510(k) clearance for Ocelot MVRX in December 2012.

Tigereye is a product line extension of our Ocelot family of image-guided CTO crossing catheters. Its design elements include an upgrade of the image capture rate to provide high definition, real-time intravascular video imaging similar to the Pantheris image-guided atherectomy system and a user-controlled deflectable tip designed to assist in steerability across the blockage. We received CE Marking for Tigereye in December 2019 and received FDA 510(k) clearance in September 2020. The product became available in the fourth quarter of 2020 for first cases in the U.S with a full commercial launch following shortly thereafter in the first quarter of 2021.

***Other Products***

Our first-generation CTO crossing catheters, Wildcat and Kittycat 2, employ a proprietary design that uses a rotational spinning technique, allowing the physician to switch between passive and active modes when navigating across a CTO. Once across the CTO, Wildcat and Kittycat 2 allow for placement of a guidewire and removal of the catheter while leaving the wire in place for additional therapies. Both products require the use of fluoroscopy solely rather than our Lumivascular (OCT-guided) platform for imaging. Wildcat was our first commercial product and has both FDA 510(k) clearance in the United States and CE Marking in Europe for crossing peripheral artery CTOs. Kittycat 2 has FDA 510(k) clearance in the United States and CE Marking in Europe for the treatment of peripheral artery CTOs. We are not expecting to sell these products in the future, as we are focusing on the promotion of our Lumivascular platform products.

**Clinical Development**

We have conducted several clinical trials to evaluate the safety and efficacy of our products in both pre-market and post-market assessments. We received FDA clearance for Ocelot CTO crossing in 2012 and for Pantheris in October 2015 for atherectomy in peripheral arteries and in November 2021 for the addition of treatment of in-stent restenosis following completion of clinical trials of the devices.

***CONNECT II (Ocelot)***

Our clinical trial for Ocelot, known as CONNECT II, was a prospective, multi-center, non-randomized trial that evaluated the safety and efficacy of Ocelot in crossing CTOs in arteries of the upper leg using OCT intravascular imaging. The CONNECT II trial enrolled 100 patients with CTOs at 13 centers in the United States and 2 centers in Europe. Patients were followed for 30 days post-procedure and an independent group of physicians verified the results to confirm the primary efficacy and safety endpoints. Results from the CONNECT II trial demonstrated that Ocelot surpassed its primary efficacy endpoint by successfully crossing the CTO in 97% of the cases following unsuccessful attempts to cross with standard guidewire techniques. Ocelot achieved these rates with 98% freedom from MAEs.

***VISION (Pantheris)***

VISION was our pivotal, non-randomized, prospective, single-arm trial to evaluate the safety and effectiveness of Pantheris across 20 sites within the United States and Europe. The objective of the clinical trial was to demonstrate that Pantheris can be used to effectively remove plaque from diseased lower extremity arteries while using on-board visualization as an adjunct to fluoroscopy. Two groups of patients were treated in VISION: (1) optional roll-ins, which are typically the first two procedures at a site, and (2) the primary cohort, which are the analyzable group of patients. The data for these two groups were reported separately in our 510(k) submission to the FDA. Based on final enrollment, the primary cohort included 130 patients. In March 2015, we completed enrollment of patients in the VISION clinical trial and we submitted for 510(k) clearance from the FDA in August 2015. In October 2015, we received 510(k) clearance from the FDA for commercialization of Pantheris. We made modifications to Pantheris subsequent to the completion of VISION and received 510(k) clearance on the enhanced version of Pantheris in March 2016 and received 501(k) clearance in May 2018 for a next-generation version of Pantheris, which includes new features and design improvements to the handle, shaft, balloon, and nose cone of the device as well as 510(k) clearance in April 2019 for Pantheris SV, a lower profile Pantheris.

VISION's primary efficacy endpoint required that at least 87% of lesions treated by physicians using Pantheris have a residual stenosis of less than 50%, as verified by an independent core laboratory. The primary safety endpoint required that less than 43% of patients experience an MAE through six-month follow-up as adjudicated by an independent Clinical Events Committee, or CEC. MAEs as defined in VISION included cardiovascular-related death, unplanned major index limb amputation, clinically driven target lesion revascularization, or TLR, heart attack, clinically significant perforation, dissection, embolus, and pseudoaneurysm. Results from the VISION trial demonstrated that Pantheris surpassed its primary efficacy and safety endpoints; residual restenosis of less than 50% was achieved in 96.3% of lesions treated in the primary cohort, while MAEs were experienced in 16.6% of patients.

Although not mandated by the FDA to support the market clearance of Pantheris, the protocol for the VISION trial allowed for routine histopathological analysis of the tissue extracted by Pantheris to be conducted. This process allowed us to determine the amount of adventitia present in the tissue, which in turn indicated the extent to which the external elastic lamina had been disrupted during Pantheris procedures. We completed histopathological analysis on tissue from 129 patients in the primary cohort, representing 162 lesions and determined that the average percent area of adventitia was only 1.0% of the total excised tissue. We believe the low level of EEL disruption will correlate to lower restenosis rates and improved long-term outcomes for patients treated with Pantheris. We published the results of the histopathological analysis in conjunction with the primary safety and efficacy endpoint data from the VISION trial.

Final VISION trial data are summarized in the table below.

| | Roll-In Cohort | Primary Cohort | Total |
|---|---|---|---|
| Patients Treated | 28 | 130 | 158 |
| | | | |
| Lesions treated | 34 | 164 | 198 |
| **Primary Efficacy Endpoint** | | | |
| Lesions analyzed by core lab | 34 | 164 | 198 |
| Lesions meeting primary efficacy endpoint criterion of residual restenosis of less than 50% by core lab | 100% | 96.3% | 97% |
| | (34/34) | (158/164) | (192/198) |
| **Primary Safety Endpoint (MAEs through 6 months)** | | | |
| Total MAEs Reported | 3 | 22 | 25 |
| Reported MAEs as a percentage of patients enrolled | 11.5% | 17.6% | 16.6% |
| | (3/26) | (22/125) | (25/151) |
| **Histopathology Results (Non-Endpoint Data)** | | | |
| Lesions with histopathology results | 34 | 162 | 196 |
| Average percent area of adventitia in all lesions with histopathology results | 0.56% | 1.02% | 0.94% |

Although the original VISION study protocol was not designed to follow patients beyond six months, in 2016 we began working with 18 of the VISION sites to re-consent patients in order for them to be evaluated for patient outcomes through 12 and 24 months following initial treatment. Data collection for patients from participating sites was completed in May 2017, and we released the final 12- and 24-month results for a total of 73 patients and 89 lesions in July 2017. The key metrics reported for this group were freedom from target lesion revascularization, or TLR, at 12 months and 24 months, which were 82% and 74% by patient and 83% and 76% by lesion, respectively, based on Kaplan-Meier curve assessments.

***INSIGHT (Pantheris)***

The INSIGHT Trial was a prospective, global, single-arm, multi-center trial to evaluate the safety and effectiveness of Pantheris for treating in-stent restenosis ("ISR") in lower extremity arteries. ISR occurs when a blocked artery previously treated with a stent becomes narrowed again, thereby reducing blood flow. Physicians often face challenges when treating ISR both in terms of safety and efficacy. From a safety standpoint, limitations in imaging techniques, such X-ray fluoroscopy, and the inability to control the directionality of other atherectomy devices create concerns with impacting the integrity of the stent during the procedure. In terms of efficacy, current therapies for in-stent restenosis, such as balloon angioplasty, have high rates of recurrent narrowing within stents.

The INSIGHT trial enrolled 97 patients at sites in the United States and Europe. Patient enrollment began in October 2017 and concluded in July 2021. Patient were evaluated at thirty days, six months and one year following treatment.

The primary safety endpoint was defined as freedom from a composite of major adverse events (MAEs) through 30 days after the procedure, as adjudicated by an independent Clinical Events Committee (CEC). The primary effectiveness endpoint was technical success, defined as the percent of target lesions that have a residual diameter stenosis ≤ 50% after use of the Pantheris device alone, as assessed by an independent angiographic core laboratory. The secondary safety endpoint was absence of new or worsening stent fracture following use of the Pantheris catheter. A secondary powered effectiveness endpoint was freedom from target lesion revascularization (TLR) at 6 months following the index procedure. Additional secondary effectiveness included procedural success, defined as the percent of target lesions that have residual diameter stenosis ≤ 30% post-Pantheris and any other adjunctive therapy, as determined by an independent core lab, and changes in Ankle- Brachial Index (ABI), and Rutherford Classes at 30 days and 6 months after the procedure in relation to the measurements prior to the procedure.

The subjects enrolled in the INSIGHT trial presented with documented symptomatic in-stent restenosis (stenosis >70% by visual estimation) and met all eligibility criteria. The target in-stent restenotic lesion had to be located in vessels with diameters of > 3 mm and < 7 mm and were not to exceed 30 cm in length. Subjects were followed through 30 days and six months post-procedure for purposes of the FDA submission to expand the indication for use statement. The clinical data for 97 subjects enrolled that reported for clinic visits 30 days and 85 subjects who reported for clinic visits 6 months after the index procedure were analyzed.

The primary safety endpoint was defined as freedom from a composite of major adverse events (MAEs) through 30 days after the procedure, as adjudicated by an independent Clinical Events Committee (CEC). Only 3 subjects (3%) experienced a MAE, with 97% of subjects free from MAEs within 30 days. With only 3% subjects reporting an MAE and a 95% one-sided upper confidence bound of 6.5%, the primary safety performance goal of MAEs occurring in < 20% of subjects was met.

The secondary safety endpoint was absence of new or worsening stent fracture following use of the Pantheris catheter. Only one (1) catheter inadvertently made contact with a stent during the 97 procedures, a rate of 1%. This endpoint was not established with a sample size requirement, so this performance goal was met not only due to its extremely low incidence rate but also by the experience that after re-training the one physician who had this event on the use of real-time optical coherence tomography imaging during the procedure, he completed 12 subsequent cases with no further events.

The primary effectiveness endpoint of this study was technical success, defined as the percent of target lesions that have a residual diameter stenosis ≤ 50% after use of the Pantheris device alone, as assessed by an independent angiographic core laboratory. In this analysis, 86 out of 97 (89%) subjects had <50% residual stenosis following use of the Pantheris catheter alone, with a 95% one-sided upper confidence bound of 95% and a lower confidence bound of 82%, which met the adjusted performance goal of > 79%.

A secondary powered effectiveness endpoint was freedom from target lesion revascularization (TLR) at 6 months following the index procedure. The freedom from TLR of the 85 subjects that have completed their 6-month follow-up visits after the index procedure was 93% (79/85), with a 95% one-sided upper confidence bound of 98% and a lower bound of 87%, which met the performance goal of > 61%.

Additional secondary effectiveness included procedural success, defined as the percent of target lesions that have residual diameter stenosis ≤ 30% post-Pantheris and any other adjunctive therapy, as determined by an independent core lab, and changes in Ankle- Brachial Index (ABI), and Rutherford Classes at 30 days and 6 months after the procedure in relation to the measurements prior to the procedure.

Procedural success was determined if the residual diameter stenosis was < 30% following adjunctive treatment. In this cohort 78 of the 97 subjects (80%) were determined to have a residual stenosis < 30% following review of angiograms by the core lab, with a mean stenosis of 15% ±10.1%.

The ABI measures improved 39% from baseline by the time of the 6-month visit and the Rutherford Classification measures improved by 71% at the same time.

Adjunctive devices used in the procedure were primarily balloons (83%), with balloon angioplasty followed by placement of a stent occurring in 13% of the cases, and no adjunctive treatment provided in 4% of the procedures.

The results from the INSIGHT trial demonstrated that the Pantheris catheter is safe and effective when used to address in-stent restenosis. The study endpoints achieved the effectiveness performance goals while demonstrating a strong safety profile indicating that the Pantheris catheter can be used to safely excise tissue from occluded vascular stents with precision. The study results also demonstrate extremely low, acute device-related adverse events.

A 510(k) application to the FDA was submitted in June and the addition of ISR treatment to the indication for use for the Pantheris catheter cleared in November 2021.

***Other Studies***

We are pursuing additional clinical data programs including a post-market study, IMAGE-BTK, that is designed to evaluate the safety and efficacy of Pantheris SV in the treatment of PAD lesions below-the-knee. We are currently enrolling patients and we expect to complete enrollment during 2022.

**Sales and Marketing**

We focus our sales and marketing efforts primarily on the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the United States that are potential users of our Lumivascular platform products. Our marketing efforts are focused on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders based on their knowledge of our products, clinical expertise and reputation. We also use continuing medical education programs and other opportunities to train interventional cardiologists, vascular surgeons, and interventional radiologists in the use of our Lumivascular platform products and educate them as to the benefits of our products as compared to alternative procedures such as angioplasty, stenting, bypass surgery or other atherectomy procedures. In addition, we work with physicians to help them develop their practices and with hospitals to market themselves as centers of excellence in PAD treatment by making our products available to physicians for treating patients.

Our sales team currently consists of a Vice President, Regional Directors, Territory Sales Managers, Clinical Specialists, and one Vice President of International Sales. Territory Sales managers are responsible for all product sales, which include disposable catheters and sale and service of our Lightbox console, while Clinical Specialists are primarily responsible for case coverage and account support. We have an extensive hands-on sales training program, focused on our technologies, Lumivascular image interpretation, case management, sales processes, sales tools and implementing our sales and marketing programs and compliance with applicable federal and state laws and regulations. Our sales team is supported by our marketing team, which focuses primarily on clinical training and education, marketing communications and product management. We have partnered with a third-party field service firm for the installation, service and maintenance of our Lightbox consoles.

For the year ended December 31, 2021, there was one customer that represented 10% of revenues. For the year ended December 31, 2020, there were no customers that represented 10% or more of revenues.

**Competition**

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions, results of clinical research, reimbursement dynamics, corporate combinations and other factors relating to our industry. Because of the market opportunity and the high growth potential of the PAD treatment market, competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products.

Our products compete with a variety of products or devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon market segments include Abbott Laboratories, AngioDynamics, Becton Dickinson, Boston Scientific, Cardinal Health, Cook Medical, Medtronic and Philips. Competitors in the atherectomy market include AngioDynamics, Boston Scientific, Cardiovascular Systems, Medtronic and Philips. Some competitors have attempted to combine intravascular imaging with atherectomy and although we are not aware of any active initiatives in this area, these and other companies may attempt to incorporate on-board visualization into their products in the future or may have ongoing programs of which we are not aware. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our solution.

Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Furthermore, many of our competitors have well-established brands, widespread distribution channels and broader product offerings, and have established stronger and deeper relationships with target customers.

To compete effectively, we have to demonstrate that our products are attractive alternatives to other devices and treatments on the basis of:

- procedural safety and efficacy;
- acute and long-term outcomes;
- ease of use and procedure time;
- third-party reimbursement;
- size, effectiveness, and productivity of sales force;
- radiation exposure for physicians, hospital staff and patients; and
- price.

**Intellectual property**

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights.

It is our policy to require our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from using the proprietary rights of third parties in their work for us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

As of December 31, 2021, we held 49 issued and allowed U.S. patents, 3 U.S. pending provisional application, 21 U.S. utility patent applications and 2 PCT applications pending. As of December 31, 2021, we also had 77 issued and allowed patents from outside of the United States. As of December 31, 2021, we had 35 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India, Japan and Mexico. As we continue to research and develop our products and technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of our devices. Our issued patents expire between the years 2028 and 2037.

Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

As of December 31, 2021, we held six registered U.S. trademarks. In Europe, we hold three registered trademarks. In the United Kingdom, we hold three registered trademarks. In addition, we held one International Registration under the Madrid Protocol with granted extensions to China, Europe, Japan, and Korea (reflected in the three European registrations noted above).

**Research and Development**

Our ongoing research and development activities are primarily focused on improving and enhancing our Lumivascular platform, specifically our core competency of integrating OCT intravascular imaging onto therapeutic catheters. Our research objectives target areas of unmet clinical need, increase the utility of the Lumivascular platform and adoption of our products by healthcare providers.

- *Product line improvements and extensions.* We are developing improvements to our Lumivascular platform, including additional catheters for use in different clinical applications. For example, we are developing next-generation CTO crossing devices to target both the peripheral and coronary CTO markets.

- *Additional treatment indications.* We intend to seek additional regulatory clearances from FDA to expand the indications for which our products can be marketed within PAD, as well as in other areas of the body. This includes both expanding the marketed indications for our current products, as well as development of new products.

- *Improved software and user interface.* We intend to further develop our software to provide more information and control to our end users during a procedure. We use physician and staff feedback to improve the features and user functionality of our Lumivascular platform

In addition to our internal team, we retain third-party contractors from time to time to provide us with assistance on specialized projects. We also work closely with experts in the medical community to supplement our internal research and development resources.

**Manufacturing**

All of our products are manufactured in-house using components and sub-assemblies fabricated both at our facility in Redwood City, California and by key qualified outside vendors. We assemble all of our finished catheter products at our manufacturing facility but certain critical processes such as coating and sterilization are done by specialized outside vendors. We expect our current manufacturing facility will be sufficient through at least 2022.

Order quantities and lead times for components purchased from outside suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. To date, we have experienced some delays in obtaining any of our components or subassemblies. Any significant delay or interruption in our supply chain could impair our ability to meet the demands of our customers and could harm our business.

We rely on single and limited source suppliers for several of our components and sub-assemblies. For example, we rely on single vendors for our optical fiber, coating and drive cables that are key components of our catheters, and we rely on single vendors for our laser and data acquisition card that are key components of our Lightbox. These components are critical to our products and there are relatively few alternative sources of supply for them. Identifying and qualifying additional or replacement suppliers for any of the components used in our products could involve significant time and cost. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components used to manufacture our products would limit our ability to manufacture our products and could therefore harm our business, financial condition and results of operations.

Our manufacturing operations are subject to regulatory requirements of 21 CFR part 820 of the Federal Food, Drug and Cosmetic Act, or FFDCA; the Quality System Regulation, or QSR, for medical devices sold in the United States, which is enforced by FDA; the Medical Devices Directive 93/42/EEC, which is required for doing business in the European Union; and applicable requirements relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal and remediation of hazardous substances, and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. We cannot ensure that we will not incur material costs or liability in connection with our operations, or that our past or future operations will not result in claims by or injury to employees or the public.

We have registered with FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. We and our component suppliers are required to manufacture our products in compliance with FDA's QSR in 21 CFR part 820 of the FFDCA. The QSR regulates extensively the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. FDA enforces the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. The audit resulted in zero observations or non-conformances. In 2018 and 2019, BSI conducted multiple routine audits including surveillance audit, Microbiology audit, a MDSAP re-certification audit and most recently, a one-day unannounced audit in September 2019. Our Quality System has undergone 20 external audits by third-parties and regulatory authorities since 2009, the latest of which was a surveillance audit conducted in January 2017 by BSI, our European Notified Body, under the Medical Device Single Audit Program, or MDSAP. All non-conformances identified in the aforementioned audits have been either successfully resolved or are being actively addressed via Avinger's CAPA system.

Our failure or the failure of our component suppliers to maintain compliance with the QSR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers fails to maintain compliance with our or governmental quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the European Union. Our Redwood City facilities meet the requirements set forth by ISO 13485:2003 Medical devices—Quality management systems—Requirements for regulatory purposes and MDD 93/42/EEC European Union Council Medical Device Directive.

**Government Regulation**

In general, medical device companies must navigate a challenging regulatory environment. In the United States the FDA regulates the medical device market to ensure the safety and efficacy of these products. The FDA allows for two primary pathways for a medical device to gain approval for commercialization: (i) a pre-market notification or 510(k) submission based upon being equivalent to a device already in commercial distribution (a predicate device) or (ii) a PMA (pre-market approval). A completely novel product must go through the more rigorous PMA process if it cannot receive authorization through a 510(k) submission. The FDA has established three different classes of medical devices that indicate the level of risk associated with using a device and consequent degree of regulatory controls needed to govern its safety and efficacy. Class I and Class II devices are considered to have minimal risk to the user. Some Class I and almost all Class II devices gain clearance for commercial distribution following review of an application to the FDA, generally known as the 510(k) process. The devices regarded as the highest risk by the FDA are designated Class III and generally require the submission of a PMA application for approval prior to commercialization. Class III devices generally include life-sustaining, life-supporting, or implantable devices or devices without a known predicate technology already approved by the FDA.

The 510(k) clearance path can be significantly less time-consuming and less arduous than PMA approval, making this route generally preferable for a medical device company. A 510(k) application must include documentation that its device is substantially equivalent to a technology already cleared through a 510(k) or in distribution before May 28, 1976, and for which the FDA has not required a PMA submission. The FDA has 90 days from the date of the pre-market equivalence acceptance to authorize or decline commercial distribution of the device. However, similar to the PMA process, clearance may take longer than this three-month window, as the FDA can request additional data to support the submission. If the FDA resolves that the product is not substantially equivalent to a predicate device, then the device acquires a Class III designation, and a PMA must be approved before the device can be commercialized. All of our currently marketed products have received commercial clearance and associated indications for use through the 510(k) regulatory pathway, some with the support of clinical data.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a change in its intended use, requires an additional 510(k) submission and clearance before the modified device can be commercialized. The FDA allows each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with the manufacturer's determination. If the FDA disagrees with the determination not to seek a new 510(k) clearance or PMA the FDA may retroactively require a new 510(k) clearance or pre-market approval for the modified device. The FDA could also require a manufacturer to cease marketing and distribution of the modified device and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, in these circumstances, a manufacturer may be subject to significant regulatory fines, penalties, and enforcement actions.

A PMA application must include reasonable scientific and clinical data that demonstrates the device is safe and effective for the intended uses and indications being sought. The application must also include preclinical testing, technical, manufacturing and labeling information. If the FDA determines the application can undergo substantive review, it has 180 days to review the submission, but it can typically take longer (up to several years) as this regulatory body can request additional information or clarifications. The FDA may also impose additional regulatory hurdles for a PMA, including the institution of an advisory panel of experts to assess the application or provide recommendations as to whether to approve the device. Although the FDA in the end approves or disapproves the device, in nearly all cases the FDA follows the recommendation from the advisory panel. As part of this process, the FDA will usually inspect the manufacturing facilities and operations prior to approval to verify compliance with quality control regulations. Significant changes in the manufacturing of a device, or changes in the intended use, indications and labeling or design of a product require new PMA applications or PMA supplements for a product originally approved under a PMA. This creates substantial regulatory risk for devices undergoing the PMA route.

***Pervasive and Continuing Regulation***

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR (quality system regulation) that requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;

- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;

- medical device reporting, or MDR, regulations, that require manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We are registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health (CDPH). The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA in 2009, 2011 and 2013, and two, three and zero observations, respectively, were noted during those inspections. In the latest FDA audit in 2013, there were no observations that involved a material violation of regulatory requirements, and no non-conformances were noted. Our responses to the observations noted in 2009 and 2011 were accepted by the FDA, and we believe that we are in substantial compliance with the QSR. BSI, our European Notified Body, inspected our facility several times between 2010 and 2015 and found zero non-conformances. BSI conducted four external audits in 2016 and zero non-conformances were found in all except for one audit, for which four minor non-conformances were found. Our Notified Body audit performed in January 2017 resulted in zero non-conformances and an unannounced audit in September 2019, noted only two minor non-conformances, that were addressed promptly and resolved. In 2015, Avinger joined the medical device-single audit program (MDSAP) that permits audits by our Notified Body to substitute for routine FDA inspections. As of the date of this filing, we have no outstanding unresolved major non-conformances or findings.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions:

- warning letters, adverse publicity, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

***Regulatory System for Medical Devices in Europe***

The system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is given CE marking that shows the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state in the EU that oversee the implementation of the EU's medical device directive, or MDD, within its jurisdiction. The means of achieving the requirements for CE marking varies according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the requirements to be fulfilled before CE marking can be placed on a product, known as a conformity assessment. Currently conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be distributed throughout the European Union without further conformance tests being required by other member states.

In March 2019, Avinger successfully transferred all current product certificates from BSI-UK to BSI-Netherlands in anticipation of the UK leaving the European Union. Our products currently with CE marking are distributed in the EU, subject to the EU's medical devices directive, or MDD with certification renewed in May 2021. In May 2021, we successfully extended the validity of the MDD certificates by 3-years, which will provide certification until we need to obtain certification under the EU's new medical device regulation, or MDR, in 2024. We have multiple ongoing efforts to update our quality management system and product technical documentation to be fully compliant with the MDR requirements before the MDD certificate expires. Until such time as we are fully certified to EU MDR, we will be highly limited in our ability to make significant product changes to existing design and intended purposes of products (for distribution in the EU only) and/or will be unable to launch new products in the EU. Such limitations could harm our business, financial condition, and operating results.

***Federal, State and Foreign Fraud and Abuse Laws***

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, which we refer to collectively as the Affordable Care Act, was enacted in the United States. The provisions of the Affordable Care Act are effective on various dates. The Affordable Care Act expands the government's investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the Anti-Kickback Statute and the False Claims Act, to make it easier to bring suit under these statutes. The Affordable Care Act also allocates additional resources and tools for the government to police healthcare fraud, with expanded subpoena power for HHS, additional funding to investigate fraud and abuse across the healthcare system and expanded use of recovery audit contractors for enforcement.

*Anti-Kickback Statutes.* The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid. Violation of the Anti-Kickback Statue is a criminal felony, and can result in criminal sanctions, civil penalties, enforcement under the False Claims Act, and exclusion from federal healthcare programs.

The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered businesses, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are otherwise lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Office of Inspector General, or OIG, of HHS to issue a series of regulations known as "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

*Federal False Claims Act.* Another development affecting the healthcare industry is the increased use of the federal False Claims Act by federal prosecutors, and in particular, action brought pursuant to the False Claims Act's "whistleblower" or "*qui tam*" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the False Claims Act and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased substantially. In addition, various states have enacted false claims laws analogous to the False Claims Act, and many of these state laws apply where a claim is submitted to any third-party payor and not just a federal healthcare program.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $11,665-$23,331 for each separate instance of false claim. As part of any settlement, the government may ask the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification, and reporting obligations. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information and other information affecting federal, state, and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

*The Sunshine Act.* The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Affordable Care Act, requires all United States manufacturers of a prescription drug, device, biologic or other medical supply that has been approved or cleared by the FDA, and is available for coverage by Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Secretary of HHS: (i) payments or other transfers of value made by that entity, or by a third-party as directed by that entity, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals; and (ii) physician ownership and investment interests in the drug and device manufacturing entity. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1,150,000). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Sunshine Act and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

*Foreign Corrupt Practices Act.* The Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

*International Laws.* In Europe, various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives, or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act of 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

***U.S. Healthcare Reform***

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenues, and impact sales of and reimbursement for our current and future solutions. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry principally by moving healthcare reimbursement towards more value-based and quality-based payment methodologies. The Act contains a number of provisions that impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in federal healthcare programs and reimbursement changes.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payors. Furthermore, the current presidential administration and Congress may again attempt broad sweeping changes to the current healthcare laws. We face uncertainties that might result from modification or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. But any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect any future legislation or regulation in the United States may have on our business.

**Third-Party Reimbursement**

Payment for patient care in the United States is generally made by third-party payors, including private insurers and government insurance programs, such as Medicare and Medicaid. The Medicare program, the largest single payor in the United States, is a federal governmental health insurance program administered by the Centers for Medicare and Medicaid Services, or CMS, and covers certain medical care expenses for eligible elderly and disabled individuals. Because a large percentage of the population with PAD includes Medicare beneficiaries, and private insurers may follow the coverage and payment policies of Medicare, Medicare's coverage and payment policies are significant to our operations.

Medicare pays PAD treatment facilities, including hospitals and physician office-based labs, pre-determined amounts for each procedure performed. These payment amounts differ based on a variety of factors, including:

- Type of procedure performed—angioplasty, stent or atherectomy;
- Patient-specific complexities and comorbidities;
- Type of facility—hospital, teaching hospital or office-based lab;
- Inpatient or outpatient status; and
- Geographic region.

We receive payment from the treatment facility for our products, and the Medicare reimbursement to the facility is intended to cover the overall cost of treatment, including the cost of products used during the procedure as well as the overhead cost associated with the facility where the procedure is performed. For procedures performed in hospitals, the physician who performs the procedure is reimbursed separately under the Medicare physician fee schedule. Claims for PAD procedures are typically submitted by the treatment facility and physician to Medicare or other health insurers using established billing codes. These codes identify the procedures performed and are relied upon to determine third-party payor reimbursement amounts.

Medicare reimbursement for hospital outpatient PAD procedures that include atherectomy for 2021 ranged between approximately $10,000 and $16,000. These amounts include the cost of disposable catheters such as Ocelot and Pantheris. While reimbursement varies based on the type of procedure performed (e.g., angioplasty, stent or atherectomy), additional device-specific reimbursement is not available. The amount of reimbursement can vary substantially by geographical region and by facility. Payment rates of other third-party payors may follow Medicare rates, or they may be higher or lower, depending on their particular reimbursement methodology. Because of the wide variability, it is not possible to identify an average rate for third-party payors other than Medicare.

**Human Capital**

As of December 31, 2021, we had 74 employees, including 22 in manufacturing and operations, 28 in sales and marketing, 7 in research and development and clinical and regulatory affairs, 5 in quality assurance and 12 in finance, general administrative and executive administration. Of these 74 employees, 6 are part time employees.

None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and we consider our employee relations to be good.

Although the COVID-19 pandemic has disrupted business and operations for companies around the globe, the resilience of our employees has enabled us to minimize disruption to our sales, research, clinical studies and operations. Our onsite employees, particularly in manufacturing and operations, have rapidly adjusted to numerous stringent safety protocols.

We are optimistic about the potential to expand our workforce and create a more inclusive environment for all of our employees.

*Diversity, Equity and Inclusion*

We understand the importance of diversity in our workforce. We will continue to focus on building a pipeline of opportunities for both the hiring and advancement of qualified individuals, including for women, persons with disabilities, and minority groups that are underrepresented in science and engineering industries. We believe that diverse perspectives will help empower our employees, patients and industry.

*Communications and Engagement*

Our success depends on employees understanding our strategic vision as well as our day-to-day objectives. To that end, we employ a mix of communication and engagement channels, including all-hands meetings, regular leadership meetings, and quarterly updates on our progress against our strategic goals. We have also created a cross-functional team focused on improving the employee experience and driving engagement.

A central part of our communications and engagement efforts are connecting people to purpose. To this end, we regularly share stories of physicians and patients that have been treated with our devices with our employees. Their experiences reinforce our commitment to expand our reach into new patient populations, geographies and markets.

*Health, Safety and Wellness*

We are deeply committed to the safety, health and wellness of our employees. The Avinger Environmental, Health & Safety team develops safety practices and procedures, trains employees, and monitors compliance. Through these efforts, along with leadership commitment and investment of resources in support of workplace safety initiatives, our total US injury rate has consistently tracked below industry averages.

*Compensation*

We recognize that our employees are our most valuable asset. Our total rewards package includes market competitive pay, comprehensive and competitive benefits and retirement offerings and paid time off and family leave, among other benefits. To foster a stronger sense of ownership and align the interests of employees with shareholders, we have offered restricted stock units to eligible employees under our broad-based stock incentive programs.

**Corporate and other Information**

We were incorporated in Delaware on March 8, 2007. Our principal executive offices are located at 400 Chesapeake Drive, Redwood City, California 94063, and our telephone number is (650) 241-7900. Our website address is www.avinger.com. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or the SEC, pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. This information may also be obtained from the SEC's on-line database, which is located at www.sec.gov. Our common stock is traded on the Nasdaq Capital Market under the symbol "AVGR".

**Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk. We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. If any of the risks actually occur, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes. Please also see "Cautionary Notes Regarding Forward-Looking Statements.*"

**Risk Factor Summary**

The risk factors summarized and detailed below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. These are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

***Risks Related to Our Business***

- significant fluctuations in our operating results, our history of net losses and ability to achieve profitability;
- our ability to obtain additional capital on acceptable terms or at all and our significant levels of debt;
- our covenants and restrictions under and our ability to service our Loan Agreement with CRG;
- our reliance on a limited number of products with a limited commercial history;
- our reliance on sales professionals to market and sell our products;
- our ability to demonstrate the benefits of our Lumivascular platform to physicians, hospitals, and patients and our ability to innovate successfully;
- our competition, which includes companies that have longer operating histories, more established products, and greater resources;
- the potential for disruptions at our manufacturing facility;
- our dependence on third-party vendors, including some single-source suppliers, to manufacture some of our components, coating, and sub-assemblies;
- our dependence on our senior management team and key employees;
- our intention not to devote significant resources in the near-term to market our Lumivascular platform internationally;
- our ability to use our net operating loss carryforwards;
- the possibility that we may acquire other companies or technologies, or be the target of strategic transactions;
- the ongoing COVID-19 pandemic and responses thereto, and its effect on customer demand;
- Disruptions of our supply chain could have a material adverse effect on our operating and financial results;
- New product development for the coronary artery disease market carries great risk

***Risks Related to Our Use of Technology and Intellectual Property***

- our technology infrastructure and the potential of a cybersecurity incident or data breach;

- any future intellectual property litigation or administrative proceedings;
- any failure to adequately protect our intellection property rights and the assertion of patents held by third parties against us;

***Regulatory and Litigation Risks***

- compliance with applicable laws and regulations and our ability to obtain necessary regulatory clearances and approvals;
- any material modifications to our Lumivascular platform products, which may require new clearances or approvals;
- certain limitations on our ability to market our current products in the United States;
- the success and timing of our clinical trials;
- the performance of the outside parties that we engage to perform services related to certain of our clinical studies;
- our limited long-term data regarding the safety and efficacy of our Lumivascular platform products;
- our suppliers' compliance with the FDA's QSR;
- any product recalls on our Lumivascular products;
- any changes in coverage and reimbursement for procedures using our Lumivascular products and any healthcare reform measures;
- compliance with healthcare regulations, environmental laws and regulations;
- regulations related to "conflict minerals" and any use, misuse, or off-label use of our products;
- the expense and availability of insurance coverage for liabilities resulting from our products;

***Risks Related to Our Organizational Structure***

- the volatility of our stock price;
- our ability to meet guidance or expectations and receive coverage of our business by securities or industry analysts;
- any sales of substantial numbers of shares of our common stock in the public market;
- the requirements and expense of being a public company;
- the possibility that Nasdaq may delist our securities from its exchange;
- anti-takeover provisions in our amended and restated certificate of incorporation, bylaws, and Delaware law;
- the forum selection clause in our amended and restated certificate of incorporation;
- our anticipation that we will not pay cash dividends in the foreseeable future;
- CRG's ability to exert significant control over certain matters pursuant to our loan agreement;
- the liquidation preference of our Series A preferred stock,
- the current number of authorized shares available for issuance, and;
- our dependence on our board of directors and related composition requirements

**Risks Related to Our Business**

***Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in decreases in the price of our common stock.***

Our quarterly and annual results of operations, including our revenues, profitability and cash flow, may vary significantly in the future and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuation in quarterly and annual results may decrease the value of our common stock. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, and the timing of such clearances and approvals, particularly with respect to current and future generations of Pantheris and Ocelot product families;
- market acceptance of our Lumivascular platform and products, including Pantheris, Ocelot and Lightbox;
- the availability of reimbursement for our Lumivascular platform products;
- our ability to attract new customers and increase the amount of business we generate from existing customers;
- results of our clinical trials;
- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, political, industry and market conditions;
- the regulatory environment;
- the hiring, training and retention of key employees, including our sales team;
- the cost and potential outcomes of any litigation;
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

In addition, we rely on estimates and forecasts of our expenses and revenues to provide guidance and inform our business strategies, and some of our past estimates and forecasts have not been accurate. The evolving nature of our business makes forecasting operating results difficult. If we fail to accurately forecast our expenses and revenues, our business, prospects, financial condition and results of operations may suffer, and the value of our business may decline. If our estimates and forecasts prove incorrect, we may not be able to adjust our operations quickly enough to respond to lower-than-expected sales which, for example, could result in higher than anticipated inventory levels, or higher-than-expected expenses which, for example, could be the result of building excess capacity.

Based upon the factors above and others beyond our control, we have a limited ability to forecast our future revenue, costs and expenses. If we fail to meet or exceed the operating results expectations of analysts and investors or if analysts and investors have estimates and forecasts of our future performance that are unrealistic or that we do not meet, the market price of our common stock could decline. In addition, if one or more of the analysts who cover us adversely change their recommendation regarding our stock, the market price of our common stock could decline. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. We may be the target of this type of litigation in the future, which could result in substantial costs and divert our management’s attention from other business concerns.

You should consider our business in light of the risks and difficulties we may encounter, as described above and elsewhere in this "Risk Factors" section. If we fail to address the risks and difficulties that we face, our business and operating results will be adversely affected.

***We have a history of net losses and we may not be able to achieve or sustain profitability.***

We have incurred significant losses in each period since our inception in 2007. We incurred net losses of $17.4 million in 2021 and $19.0 million in 2020. As of December 31, 2021, we had an accumulated deficit of approximately $384.8 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivascular platform and acquire customers.

We expect our losses to continue for the foreseeable future as we continue to make significant future expenditures to develop and expand our business. In addition, as a public company, we will continue to incur significant legal, accounting and other expenses. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

***We may not be able to secure additional financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our product development programs and commercialization efforts or cause us to become insolvent.***

We believe that our cash and cash equivalents at December 31, 2021, together with debt and financing activities, including the financing in January 2022, and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations through at least the second quarter of 2023. Even though we received net proceeds of approximately of $3.9 million from the sale of our common stock in our January 2020 offering, $2.3 million of loan proceeds in April 2020 pursuant to the Paycheck Protection Program ("PPP") under the Coronavirus Aid, Relief and Economic Security ("CARES") Act, $3.0 million from the sale of our common stock in April and May 2020, $5.5 million from the sale of our common stock in June and July 2020, $11.3 million from the sale of our common stock in August and September 2020, approximately $13.0 million from the sale of our common stock in February 2021, and approximately $6.7 million from the sale of our Series D Convertible Preferred Stock and common stock purchase warrants in a registered direct offering in January 2022, we may need to raise additional funds through future equity or debt financings in the near future to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the volatility of our stock price, any financing that we undertake could cause substantial dilution to our existing stockholders.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our initial public offering, or IPO, and our follow-on public offerings. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivascular platform products, (iii) expand our sales and marketing infrastructure, (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

- the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris, and any future versions of such products;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products;
- the costs and expenses of maintaining or expanding our sales and marketing infrastructure and our manufacturing operations;
- the costs and timing of developing variations of our Lumivascular platform products and, if necessary, obtaining FDA clearance of such variations;
- the extent to which our Lumivascular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD;
- the number and types of future products we develop and commercialize;
- the costs of defending ourselves against future litigation;

- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and

- the extent and scope of our general and administrative expenses.

We may raise additional funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. In addition, due to our current level of debt, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. If we raise additional funds through further issuances of equity or convertible debt securities, and/or if we convert all or a portion of our existing debt to equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, and significantly scale back our operations, or we may become insolvent. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

***We have a significant amount of debt, which may adversely affect our ability to operate our business and our financial position and our ability to secure additional financing in the future.***

As of December 31, 2021, we had $12.3 million in principal, back-end fees and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"). Our significant amount of debt may:

- increase our vulnerability to adverse changes in general economic, industry and competitive conditions;

- require us to dedicate a substantial portion of our cash flow from operations to make payments on our debt, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;

- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;

- restrict us from exploiting business opportunities;

- make it more difficult to satisfy our financial obligations, including payments on the Loan Agreement;

- place us at a competitive disadvantage compared to our competitors that have less debt obligations; and

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general corporate purposes on satisfactory terms or at all.

The existence of a substantial amount of debt may make it difficult for us to run our business effectively or raise the capital we need to continue our operations.

***Covenants under the Loan Agreement will restrict our business in many ways.***

The Loan Agreement contains various covenants that limit, subject to certain exceptions, our ability to, among other things:

- incur or assume liens;

- incur additional debt or provide guarantees in respect of obligations of other persons;

- issue redeemable stock and preferred stock;

- pay dividends or make distributions on capital stock, repurchase, redeem or make payments on capital stock or repay, repurchase, redeem, retire, defease, acquire or cancel debt prior to the stated maturity thereof;

- make loans, investments or acquisitions;

- create or permit restrictions on the ability of our subsidiaries to pay dividends or make other distributions to us or to guarantee our debt, limit our or any of our subsidiaries ability to create liens, or make or pay intercompany loans or advances;

- enter into certain transactions with affiliates;

- sell, transfer, license, lease or dispose of our or our subsidiaries' assets, including the capital stock of our subsidiaries; and

- dissolve, liquidate, consolidate or merge with or into, or sell substantially all of our assets to another person.

In particular, the Loan Agreement, as most recently amended in January 2021, includes a covenant that we maintain a minimum of $3.5 million of cash and certain cash equivalents, and we will have to achieve minimum revenues of $8.0 million in 2021, $10.0 million in 2022, $12.0 million in 2023, $14.5 million in 2024 and $17.0 million in 2025. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. There can be no assurance as to our future compliance with the covenants under the Loan Agreement, as amended.

The covenants contained in the Loan Agreement could adversely affect our ability to execute our business strategies by restricting our ability to make capital expenditures, engage in strategic acquisitions, refinance our outstanding indebtedness, or obtain additional financing. Such restrictions may make it difficult to plan for or react to changes in market conditions, such as future downturns in our business or the economy in general.

In addition, potential sources of equity financing may decline to invest in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. In order to facilitate equity investments, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result.

***We may not be able to generate sufficient cash to service our Loan Agreement. If we default on payments or otherwise fail to comply with our obligations under our Loan Agreement, the lender may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.***

Borrowings under our Loan Agreement are secured by substantially all of our personal property, including our intellectual property. The existing collateral pledged under the Loan Agreement may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions. Our ability to make scheduled payments, comply with our debt covenants, or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to numerous risks, including the risks in this section, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of the Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated. If we fail to comply with our obligations under the Loan Agreement, the lender would be able to accelerate the required repayment of amounts due and, if they are not repaid, could foreclose upon our assets securing our obligations under the Loan Agreement.

***Our success depends in large part on a limited number of products, particularly Pantheris product family, all of which have a limited commercial history. If these products fail to gain, or lose, market acceptance, our business will suffer.***

Ocelot, Ocelot PIXL, Ocelot MVRX, Tigereye, Lightbox 3, Pantheris and Pantheris SV are our only products currently cleared for sale, and our current revenues are wholly dependent on them. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of the Pantheris product family and we expect that sales of our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Lumivascular platform products by the medical community.

All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA clearance to market enhanced versions of Pantheris in March 2016 and May 2018 and those versions of Pantheris became commercially available in the United States and select international markets promptly thereafter. Pantheris SV launched in July 2019 after having received FDA clearance in April 2019. Tigereye launched in October 2020 after having received FDA clearance in September 2020. Our limited commercialization experience and number of approved products make it difficult to evaluate our current business and predict our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by companies in rapidly-changing industries.

Our ability to successfully market Lumivascular platform products will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure demand for Lumivascular platform products will continue to grow or that our products will significantly penetrate current or new markets. Market demand for our Lumivascular platform products and physician adoption of these products also may be negatively impacted by product performance issues and the need to replace certain products in accordance with our warranty policy. Utilization of our products has been less than we anticipated historically. If demand for our Lumivascular platform products does not increase and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivascular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivascular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivascular platform products. Any studies we may conduct comparing our Lumivascular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivascular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivascular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize our products, would harm our business, financial condition and results of operations.

We are also aware of certain characteristics and features of our Lumivascular platform that may prevent widespread market adoption. For example, in procedures using the current model of Pantheris, some physicians may prefer to have a technician or second physician assisting with the operation of the catheter as well as a separate technician to operate the Lightbox, potentially making it less financially attractive for physicians and their hospitals and medical facilities. It may take significant time and expense to modify our products to allow a single physician to operate the entire system and we can provide no guarantee that we will be able to make such modifications or obtain any additional and necessary regulatory clearances for such modifications. Although the OCT images created by our Lightbox may make it possible for physicians to reduce the degree to which fluoroscopy and contrast dye are used when using our Lumivascular platform products compared to competing endovascular products, physicians are still using both fluoroscopy and contrast dye in these procedures. As a result, risks of complications from radiation and contrast dye are still present and may limit the commercial success of our products. Finally, it requires training of technicians and physicians to effectively operate our Lumivascular platform products, including interpreting the OCT images created by our Lightbox, which may affect adoption of our products by physicians.

Our Lumivascular products are highly complex and the failure of relatively minor components could result in product failure or other significant performance issues that may not be discovered until after delivery to customers, which could give rise to claims from our customers or their patients. We have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have attempted to address certain of these concerns with our current version of Pantheris. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised by earlier versions of Pantheris. Our revenue has been adversely impacted by these product performance issues. We also had to incur additional expenses to make product changes and improvements, and to replace products in accordance with our warranty policy. If future product performance issues are not resolved and physician concerns not addressed, our reputation could suffer, which could lead to decreased sales of our products.

***We rely heavily on our sales professionals to market and sell our products. If we are unable to hire, effectively train, manage, improve the productivity of, and retain our sales professionals, our business will be harmed, which would impair our future revenue and profitability.***

Our success largely depends on our ability to hire, train, manage and improve the productivity levels of our sales professionals. We have experienced turnover of our sales professionals in the past. The loss of any member of our sales team’s senior management could weaken our sales expertise and harm our business, and we may not be able to find adequate replacements on a timely basis, or at all. The changes in senior management that have occurred over the past several years may continue to create instability in our sales force leading to attrition in sales representatives in the future.

Competition for sales professionals who are familiar with and trained to sell our products continues to be strong. We train our sales professionals to better understand our existing and new product technologies and how they can be positioned against our competitors' products. These initiatives are intended to improve the productivity of our sales professionals and our revenue and profitability. It takes time for the sales professionals to become productive following their hiring and training and there can be no assurance that sales representatives will reach adequate levels of productivity, or that we will not experience significant levels of attrition in the future. Measures we implement to improve the productivity may not be successful and may instead cause additional departures from our sales organization, or further reduce our revenue, profitability, and harm our business and our stock price may be adversely impacted as a result.

***Our ability to compete is highly dependent on demonstrating the benefits of our Lumivascular platform to physicians, hospitals and patients and our ability to innovate new and improved products.***

In order to generate sales, we must be able to clearly demonstrate that our Lumivascular platform is a more effective treatment system than the alternatives offered by our competitors. If we are unable to convince physicians that our Lumivascular platform leads to significantly lower rates of restenosis, or narrowing of the artery, and leads to fewer adverse events during treatment than those using competing technologies, our business will suffer. We must convince hospitals and physicians that our Lumivascular platform results in significantly better patient outcomes at a competitive overall cost. For example, we may need to demonstrate that the investment hospitals must make if purchasing our Lightbox and the incremental costs of having a technician or a second individual operate Pantheris can be justified based on the benefits to patients, physicians and hospitals. If we are unable to develop robust clinical data to support these claims, we will be unable to convince hospitals and third-party payors of these benefits and our business will suffer.

Our value proposition to physicians and hospitals is largely dependent upon our contention that the rate of arterial damage when physicians are using our imaging products is lower than with non-imaging competing products. If minimizing arterial damage does not significantly impact patient outcomes, meaning either (i) that restenosis is often triggered without disrupting healthy arterial structures or (ii) arteries can be damaged during treatment without triggering restenosis, then we may be unable to demonstrate our Lumivascular platform's benefits are any different than competing technologies. Furthermore, physicians may find our imaging system difficult to use, and we may not be able to provide physicians with adequate training to be able to realize the benefits of our Lumivascular platform. If physicians do not value the benefits of on-board imaging and the enhanced visualization enabled by our products during an endovascular intervention as compared to our competitors' products, or do not believe that such benefits improve clinical outcomes, our Lumivascular platform products may not be widely adopted.

In order to remain competitive, we must also continue to develop new product offerings and enhancements to our existing Lumivascular platform products. The market for medical devices in general, and in the PAD market in particular, is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. If we are unable to innovate successfully, our Lumivascular platform products could become obsolete and our revenues would decline as our customers purchase our competitors' products. In addition, our innovation efforts may not result in new products that generate additional revenue. For example, we believe that our next-generation Pantheris and Pantheris SV are important to our future revenues, and we are devoting a significant portion of our resources to their continued development. However, we do not yet know whether these or any other new offerings will be well received and broadly accepted by physicians, and if so, whether sales will be sufficient for us to offset costs of development, implementation, support, operation, sales and marketing. Additionally, new products may subject us to additional risks of product performance, market adoption, customer complaints and litigation. If sales of our new product offerings, including are lower than we expect, fail to gain anticipated market acceptance or cause us to expend additional resources to fix unforeseen problems and develop modifications, our revenues and results of operations may not improve and our business will be adversely affected.

***Our ability to develop, market, and sell our products depends in part upon our working relationships with physicians, and any events that damage those relationships, or make it more difficult to build and maintain those relationships, could harm our business.***

The development, marketing, and sale of our products depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations. The medical device industry's relationship with physicians is under increasing scrutiny by the Office of Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Changes to or our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies, could significantly harm our business by damaging our reputation among, or restricting our ability to work with, physicians.

In addition, we target our sales efforts to interventional cardiologists, vascular surgeons and interventional radiologists because they are often the physicians diagnosing and treating both coronary artery disease and PAD. If these physicians are not made aware of our Lumivascular platform products, those patients may instead be surgically treated or treated with an alternative interventional procedure. In addition, there is a significant correlation between PAD and coronary artery disease, and many physicians do not routinely screen for PAD while screening for coronary artery disease. If we are not successful in educating physicians about screening for PAD and about the capabilities of our Lumivascular platform products, our ability to increase our revenues may be impaired.

***We compete against companies that have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration, increasing our revenues or becoming profitable.***

Our products compete with a variety of products and devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon markets include Abbott Laboratories, AngioDyamics, Boston Scientific, Cardinal Health, Cook Medical, Becton Dickinson and Medtronic. Competitors in the atherectomy market include AngioDyamics, Boston Scientific, Cardiovascular Systems, Medtronic and Philips. Some competitors have previously attempted to combine intravascular imaging with atherectomy and may have current programs underway to do so. These and other companies may attempt to incorporate on-board visualization into their products in the future and may remain competitive with us in marketing traditional technologies. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our products. Many of our competitors have significantly greater financial and other resources than we do and have well-established reputations, as well as broader product offerings and worldwide distribution channels that are significantly larger and more effective than ours. In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenues to decline and would harm our business. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

If we are unable to effectively differentiate our products or company from those of our competitors and our business may be adversely affected.

***If our manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, or our electronic systems are compromised, our ability to manufacture and sell our Lumivascular platform products and to pursue our research and development efforts may be jeopardized.***

We currently manufacture and assemble our Lumivascular platform products in-house. Our products are comprised of components sourced from a variety of contract manufacturers, with final assembly completed at our facility in Redwood City, California. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, terrorism, flooding and power outages. Further, our electronic systems may experience service interruptions, denial-of-service and other cyber-attacks, computer viruses or other events. Any of these may render it difficult or impossible for us to manufacture products, pursue our research and development efforts or otherwise run our business for some period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products.

***We depend on third-party vendors to manufacture some of our components, coating and sub-assemblies, including some single source suppliers, which could make us vulnerable to supply shortages and price fluctuations that could harm our business.***

We currently manufacture some of our components and sub-assemblies at our Redwood City facility and rely on third-party vendors for other components and sub-assemblies used in our Lumivascular platform. For several of our components and sub-assemblies we rely on single and limited source suppliers. For example, we rely on single vendors for our optical fiber, coatings and drive cables that are key components of our catheters, and we rely on single vendors for our laser and data acquisition card that are key components of our Lightbox. These components are critical to our products and there are relatively few alternative sources of supply. Further, we do not carry a significant inventory of these components. Our reliance on third-party vendors subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in shipments resulting from slowdowns in manufacturing due to the COVID-19 pandemic or other causes, such as government restrictions on the movement of people and goods;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to consistently produce quality components;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative or additional suppliers for components in a timely manner;
- inability of the manufacturer or supplier to comply with QSR as enforced by the FDA and state regulatory authorities;
- inability to control the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

The ongoing COVID-19 pandemic, including subsequent variants, and measures taken in response by governments and businesses worldwide to contain its spread, including quarantines, facility closures, travel and logistics restrictions, border controls, and shelter in place or stay at home and social distancing orders, have adversely impacted and are expected to continue to adversely impact global supply chain, manufacturing, and logistics operations. Shipping and freight delays have also been increasing as port closures, port congestion, and shipping container and ship shortages have increased. To the extent the COVID-19 pandemic and other events result in continuation or worsening of manufacturing and shipping delays and constraints, our suppliers of raw materials and other components may have difficulty obtaining and providing the materials we require to manufacture our products, which could adversely affect our ability to acquire and maintain adequate inventory and meet demand for our products. In addition, any significant delay or interruption in the supply of components or sub-assemblies, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business.

***We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.***

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business.

We must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales professionals. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines or if we do not make grants of stock-based incentive awards, it may harm our ability to recruit and retain highly skilled employees. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business would be harmed.

***We do not currently intend to devote significant additional resources in the near-term to market our Lumivascular platform internationally, which will limit our potential revenues from our Lumivascular platform products.***

Marketing our Lumivascular platform outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our product development and regulatory strategy, we plan to expand into select international markets, but we do not currently intend to devote significant additional resources to market our Lumivascular platform internationally in order to focus our resources and efforts on the U.S. market. Our decision to market our products primarily in the United States in the near-term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our Lumivascular platform products or other products internationally.

***Our ability to utilize our net operating loss carryforwards may be limited.***

As of December 31, 2021, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $334.4 million and $204.8 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2024 for state purposes. Out of the total Federal net operating loss carryforwards, $76.9 million were generated in years after December 31, 2017 and have no expiration. Subject to certain limitations, NOLs can be used to offset taxable income for U.S. federal income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. It is possible that prior transactions with respect to our stock may have caused, and that future issuances or sales of our stock (including certain transactions involving our stock that are outside of our control) could cause, an “ownership change.” A number of our common and preferred stock financings over the past year may affect our ability to use NOLs. If an “ownership change” occurs, Section 382 would impose an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could (depending on the extent of such limitation and the NOLs previously used) result in our retaining less cash after payment of U.S. federal income taxes during any year in which we have taxable income (rather than losses) than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income tax reporting purposes, which could harm our profitability. On December 22, 2017, the Tax Cuts and Jobs Act, or Tax Act, was enacted into law with many significant changes to the U.S. tax laws. The Tax Act limits the utilization of NOLs arising in tax years beginning after December 31, 2017 to 80% of taxable income per year. However, existing NOLs that arose in years prior to December 31, 2017 are not affected by these provisions. Our ability to utilize NOLs arising in future tax periods may be limited by the Tax Act.

***The ongoing COVID-19 pandemic and responses thereto have adversely affected and we expect will continue to adversely affect our supply chain, workforce, approval process, and business operations.***

The ongoing COVID-19 pandemic, and related government and social responses, have resulted in widespread impacts on our industry and the economy in general, including closures of businesses not deemed “essential,” limitations on the availability of elective medical procedures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, as well as record declines in stock prices, among other effects. We continue to monitor our operations and government mandates and may elect or be required to temporarily close our offices to protect our employees, and limit our access to customers and limit customer use of our products as they are required to prioritize resources to address the public healthcare needs arising from the COVID-19 pandemic. Such disruptions to our activities and operations will negatively impact our business and some of our operating results and may negatively impact our financial condition.

The duration of COVID-19's impact on our business may be difficult to assess or predict. The widespread pandemic has resulted, and may continue to result for an extended period, in significant disruption of global financial markets, reducing our ability to access capital, which would negatively affect our liquidity. Further, quarantines or government reaction or shutdowns could disrupt our supply chain. Travel and import restrictions may also disrupt our ability to manufacture or distribute our devices. Any import or export or other cargo restrictions related to our products or the raw materials used to manufacture our products would restrict our ability to manufacture and ship products and harm our business, financial condition and results of operations. Our key personnel and other employees could also be affected by COVID-19, potentially reducing their availability, and an outbreak such as COVID-19 or the procedures we take to mitigate its effect on our workforce could reduce the efficiency of our operations or prove insufficient. We may delay or reduce certain spending related to certain projects until the travel and logistical impacts related to COVID-19 are lifted, which will delay the completion of such projects.

In addition, the conduct of clinical trials required to obtain clearance of additional indications and studies gathering post-market data for some of our products previously cleared by the FDA have been, and we expect may continue to be, affected by the COVID-19 pandemic. Specifically, site initiation and patient enrollment were delayed for one of our clinical studies, and we experiencing delays in completing the INSIGHT clinical study with the restrictions on clinical work. As hospital resources are prioritized for the COVID-19 outbreak and quarantines impede patient movement or interrupt healthcare services, these and other clinical studies may continue to be disrupted. If we are unable to successfully complete these or other clinical studies, and thus obtain regulatory approvals and efficacy data sought, our business and operating results may be harmed.

While certain jurisdictions have eased or entirely lifted restrictions on performing elective procedures, we cannot be certain that other jurisdictions will do so, or that, as hospitals continue to ease restrictions on elective procedures, patients will begin requesting such procedures. Furthermore, some jurisdictions have experienced and continue to experience a resurgence in COVID-19 cases, which has prompted certain hospitals and other medical providers in such areas to again defer elective procedures or further prolong or reinstate restrictions on such procedures. If other jurisdictions experience a resurgence in COVID-19 cases, they may also prolong or reinstate restrictions on elective procedures.

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak is highly uncertain and subject to change, and its duration and extent depends on factors such as the evolution of variants of the virus, and the development and widespread distribution of vaccines. We do not yet know the full extent of potential delays or impacts on our business or the global economy as a whole. However, these effects have harmed our business, financial condition, and results of operations in the near term and could have a continuing material impact on our operations, sales, and ability to continue operations.

***Customer demand for and our ability to sell and market our products have been and we expect will continue to be adversely affected by the COVID-19 pandemic and responses thereto.***

Restrictions on the ability to travel, social distancing policies, orders and restrictions, including those described above, and recommendations and fears of COVID-19 spreading within medical centers has caused both patients and providers to delay or cancel procedures that use our devices. We are unable to accurately predict when these policies, orders and restrictions will be relaxed or lifted, and there can be no assurances that patients or providers will restart procedures that use our devices upon termination of these policies, orders and restrictions, particularly if there remains any continued community outbreak of COVID-19. A prolonged economic contraction or recession may also result in employer layoffs of their employees in markets where we conduct business, which could result in lower procedure demand.

Our sales and marketing personnel often rely on in-person and onsite access to healthcare providers which is currently restricted as hospitals reduce access to essential personnel only. These restrictions have harmed our sales and marketing efforts, and continued restrictions would have a negative impact on our sales and results of operations. An increase of COVID-19-related hospital admissions may overload hospitals with unexpected patients, thereby delaying further procedures that use our devices but that are deemed elective by the hospital. In addition, we made temporary salary and work hour reductions, though we have reverted salaries and hours to prior levels, we and may, in the future, take further actions including reinstating reductions to salary and work hours, furloughs, restructuring or layoffs, which may negatively impact our workforce and our business.

***Disruptions of our supply chain could have a material adverse effect on our operating and financial results***

Disruption of our supply chain capabilities due to trade restrictions, political instability, severe weather, natural disasters, public health crises such as the ongoing COVID-19 pandemic, terrorism, product recalls, port closures, labor supply or stoppages, the financial or operational instability of key suppliers and carriers, government restrictions or measures, or other reasons could impair our ability to distribute our products. Many industries, including our own, face supply chain challenges as a result of COVID-19 and other macroeconomic issues, including reduced freight availability and increased costs, port disruption, manufacturing facility closures, labor shortages and other supply chain disruptions. To the extent we are unable to mitigate the likelihood or potential impact of such events, there could be a material adverse effect on our operating and financial results. We have and continue to experience supply chain challenges resulting from COVID-19, specifically related to extended lead times from certain key suppliers. Should these challenges persist or worsen, we may be unable to manufacture enough inventory to meet the current demand for our Lumivascular products and consequently incur significant adverse effects on our operating and financial results.

***We may acquire other companies or technologies or be the target of strategic transactions, which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.***

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our Lumivascular platform, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, our technology and product development efforts have been organic, and we have no experience in acquiring other businesses. In any acquisition, we may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following the acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

In addition, we sometimes receive inquiries relating to potential strategic transactions, including from third parties who may seek to acquire us. We will continue to consider and discuss such transactions as we deem appropriate. Such potential transactions may divert the attention of management, and cause us to incur various costs and expenses in investigating and evaluating such transactions, whether or not they are consummated.

***New product development for the coronary artery disease market may be challenging, expensive and carries no guarantee of an approved commercial product.***

In order to create more opportunities to grow our revenue base, we must continue to develop new product offerings and enhancements to our existing Lumivascular platform products. The market for medical devices in general, and in the coronary artery disease ("CAD") market, is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. We believe that a Lumivascular product developed for the CAD market is important to our future revenues, and we are beginning to devote a significant portion of our resources to its development. Consequently, we anticipate we will need additional capital to finance this endeavor encompassing the research and development, clinical trials and eventual promotion of any new CAD product. Even if we are able to obtain additional capital, we may not be successful in the development any new CAD product.

Our team may not have all the necessary qualifications and experience for the development of such a product. Therefore, we may need to attract and retain highly qualified personnel with specific experience in the coronary industry. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing these types of medical devices, and we may not be successful in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. We may also may not be able to complete development of such products or choose to allocate our financial and other resources elsewhere due to unforeseen circumstances.

Should we develop a CAD product, we will need to conduct a clinical trial. Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that this product may ultimately prove unsafe or ineffective in treating the indications for which they it will be designed. Completion of clinical trials may take several years or more and failure of the trial can occur at any time. We cannot provide any assurance that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. Even if we achieve positive early or preliminary results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not indicate success in later trials. Many companies in the medical device industry have suffered significant setbacks in late-stage clinical trials, even after receiving promising results in earlier trials or in the preliminary results from these late-stage clinical trials.

Furthermore, we do not yet know whether any new CAD product, if developed and approved, will be well received and broadly accepted by physicians, and if so, whether sales will be sufficient for us to offset costs of development, implementation, support, operation, sales and marketing. Additionally, such products may subject us to additional risks of product performance, market adoption, customer complaints and litigation. If sales of this coronary device are lower than we expect, fail to gain anticipated market acceptance or cause us to expend additional resources to fix unforeseen problems and develop modifications, our revenues and results of operations may not improve and our business will be adversely affected.

**Risks Related to Our Use of Technology and Intellectual Property**

***If our technology infrastructure is compromised, damaged or interrupted by a cybersecurity incident, data security breach or other security problems, our operating results and financial condition could be adversely affected.***

We use technology in substantially all aspects of our business operations, and our ability to serve customers most effectively depends on the reliability of our technology systems. Cybersecurity incidents can include computer viruses, computer denial-of-service attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage.

In addition, our technology infrastructure and systems are vulnerable to damage or interruption from natural disasters, power loss and telecommunications failures. Any such disruption to our systems, or the technology systems of third parties on which we rely, the failure of these systems to otherwise perform as anticipated, or the theft, destruction, loss, misappropriation, or release of sensitive and/or confidential information or intellectual property, could require us to notify affected individuals, federal or state agencies or media outlets of the incident and could result in business disruption, negative publicity, loss of customers, potential liability, including litigation or other legal actions against us or the imposition of penalties, fines, fees or liabilities, which may not be covered by our insurance policies, and competitive disadvantage, any or all of which would potentially adversely affect our customer service, decrease the volume of our business and result in increased costs and lower profits. Moreover, a cybersecurity breach could require us to devote significant management resources to address the problems associated with the breach and to expend significant additional resources to upgrade further the security measures we employ to protect information against cyber-attacks and other wrongful attempts to access such information, which could result in a disruption of our operations.

While we have invested, and continue to invest, in technology security initiatives and other measures to prevent security breaches and cyber incidents, as well as disaster recovery plans, these initiatives and measures may not be entirely effective to insulate us from technology disruption that could result in adverse effects on our results of operations.

***We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our Lumivascular platform products.***

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include hardware and software components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. They may devote substantial resources towards obtaining claims that cover the design of our atherectomy products to prevent the marketing and selling of competitive products. We may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third-party intellectual property rights being asserted against us. The defense and prosecution of these matters are both costly and time consuming. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our Lumivascular platform products to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination, inter partes review, or opposition proceedings, before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our Lumivascular platform products or using product names, which would have a significant adverse impact on our business.

Additionally, we may need to commence proceedings against others to enforce our patents or trademarks, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or similar to our products or from using product names that are the same or similar to our product names, and our business may be harmed as a result.

***We are aware of patents held by third parties that may be asserted against us in litigation that could be costly and could limit our ability to sell our Lumivascular platform products.***

We are aware of patent families related to catheter positioning, optical coherence tomography, occlusion cutting and atherectomy owned by third parties. With regard to atherectomy patents, one of our founders, Dr. John Simpson, founded FoxHollow Technologies prior to founding our company. FoxHollow Technologies developed an atherectomy device that is currently sold by Medtronic, and Dr. Simpson and our Chief Technology Officer, Himanshu Patel, are listed as inventors on patents covering that device that are now held by Medtronic. We are not currently aware of any claims Medtronic has made or intends to make against us with respect to Pantheris or any other product or product under development. Because of a doctrine known as “assignor estoppel,” if any of Dr. Simpson’s earlier patents are asserted against us by Medtronic, we may be prevented from asserting an invalidity defense regarding those patents, and our defense may be compromised. Medtronic has significantly greater financial resources than we do to pursue patent litigation and could assert these patent families against us at any time. Adverse determinations in any such litigation could prevent us from manufacturing or selling Pantheris or other products or products under development, which would significantly harm our business.

***Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.***

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2021, we held 49 issued and allowed U.S. patents, 3 U.S. pending provisional application, 21 U.S. utility patent applications and 2 PCT applications pending. As of December 31, 2021, we also had 77 issued and allowed patents from outside of the United States. As of December 31, 2021, we had 35 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India, Japan and Mexico. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business.

We use certain open source software in all versions of our Lightbox. We may face claims from companies that incorporate open source software into their products or from open source licensors, claiming ownership of, or demanding release of, the source code, the open source software or derivative works that were developed using such software, or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to cease offering Lightbox unless and until we can re-engineer it to avoid infringement. This re-engineering process could require significant additional research and development resources, and we may not be able to complete it successfully. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and operating results.

**Regulatory and Litigation Risks**

***If we fail to obtain and maintain necessary regulatory clearances or approvals for our Lumivascular platform products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.***

Our Lumivascular platform products are medical devices that are subject to extensive regulation by FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- pre-marketing clearance or approval;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for, an existing product can be marketed in the United States, a company must first submit and receive either 510(k) clearance or pre-marketing approval from FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearance to market our Pantheris family of catheters for atherectomy, and our Ocelot family of catheters for crossing sub and total occlusions in the peripheral vasculature, our clearance can be revoked if safety or efficacy problems develop. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth.

In addition, we are required to timely file various reports with the FDA, including medical device reports, or MDRs, if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these MDRs are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall that could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including Warning Letters, adverse publicity, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include, among other things, harm to our reputation; fines, injunctions, civil penalties, or criminal prosecution; product replacements or recalls; or rejecting our requests for future 510(k) clearance or pre-market approval or withdrawal of a previously granted 510(k) clearance. If any of these events were to occur, our business and financial condition would be harmed.

***Material modifications to our Lumivascular platform products may require new 510(k) clearances or pre-market approvals or may require us to recall or cease marketing our Lumivascular platform products until clearances or approvals are obtained.***

Material modifications to the intended use or technological characteristics of our Lumivascular platform products will require new 510(k) clearances or pre-market approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained if such changes were made via the "Letter-to-File" process of internal documentation. Based on published FDA guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a pre-market approval. We may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, our Lumivascular platform products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our Lumivascular platform products in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our Lumivascular platform products as modified, which could harm our operating results and require us to redesign our Lumivascular platform products. In these circumstances, we may be subject to significant enforcement actions. Future versions of are Lumivacular platform incorporating enhancements may require additional regulatory clearances or approvals.

***Our ability to market our current products in the United States is limited to use in peripheral vessels, and if we want to market our products for other uses, we will need to file for FDA clearances or approvals and may need to conduct trials to support expanded use, which would be expensive, time-consuming and may not be successful.***

Our current products are cleared in the United States only for crossing sub-total and chronic total occlusions and for performing atherectomy in the peripheral vasculature. These FFDCA clearances prohibits us from marketing or advertising our products for any other indication within the peripheral vasculature, which restricts our ability to sell these products and could affect our growth. Additionally, our products are contraindicated for use in the cerebral, carotid, coronary, iliac, and renal arteries. While off-label use of medical devices is common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications regarding such off-label use. We are not allowed to actively promote or advertise our products for off-label use. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings or enforcement action by the FDA and other government agencies. In the future, if we want to market a variation of Ocelot or Pantheris product families in the United States for use in other applications for which we do not currently have clearance, such as the coronary arteries, we will need to make modifications to these products, conduct further clinical trials and obtain new clearances or approvals from the FDA. There can be no assurance that we will successfully develop these modifications, that future clinical studies will be successful or that the expense of these activities will be offset by additional revenues.

***If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.***

Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more and failure of the trial can occur at any time. We cannot provide any assurance that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. Even if we achieve positive early or preliminary results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not indicate success in later trials. Many companies in the medical device industry have suffered significant setbacks in late-stage clinical trials, even after receiving promising results in earlier trials or in the preliminary results from these late-stage clinical trials.

We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, including new indications for existing products, including:

- negative or inconclusive results that may cause us to decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;
- trial results that do not meet the level of statistical significance required by the FDA or other regulatory authorities;
- findings by the FDA or similar foreign regulatory authorities that the product is not sufficiently safe for investigational use in humans;
- interpretations of data from preclinical testing and clinical testing by the FDA or similar foreign regulatory authorities that may be different from our own;
- delays or failure to obtain approval of our clinical trial protocols from the FDA or other regulatory authorities;
- delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- findings by the FDA or similar foreign regulatory authorities that our or our suppliers' manufacturing processes or facilities are unsatisfactory;
- changes in the review policies of the FDA or similar foreign regulatory authorities or the adoption of new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- trouble in managing multiple clinical sites;
- delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and
- the suspension or termination by us, or regulators, of our clinical trials because the participating patients are being exposed to unacceptable health risks.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position.

***From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials, and any failure of those parties to fulfill their obligations could increase costs and cause delays.***

From time to time, we engage consultants to help design, monitor, and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to help facilitate the clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, commonly referred to as good clinical practices. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances that we need to commercialize our products.

***We have limited long-term data regarding the safety and efficacy of our Lumivascular platform products, including Pantheris. Any long-term data that is generated by clinical trials involving our Lumivascular platform may not be positive or consistent with our short-term data, which would harm our ability to obtain clearance to market and sell our products.***

Our Lumivascular platform is a novel system, and our success depends on its acceptance by the medical community as being safe and effective, and improving clinical outcomes. Important factors upon which the efficacy of our Lumivascular platform products, including Pantheris, will be measured are long-term data on the rate of restenosis following our procedure, and the corresponding duration of patency, or openness of the artery, and publication of that data in peer-reviewed journals. Another important factor that physicians will consider is the rate of reintervention, or retreatment, following the use of our Lumivascular platform products. The long-term clinical benefits of procedures that use our Lumivascular platform products are not known.

The results of short-term clinical experience of our Lumivascular platform products do not necessarily predict long-term clinical benefit. Restenosis rates typically increase over time. We believe that physicians will compare the rates of long-term restenosis and reintervention for procedures using our Lumivascular platform products against alternative procedures, such as angioplasty, stenting, bypass surgery and other atherectomy procedures. If the long-term rates of restenosis and reintervention do not meet physicians' expectations, our Lumivascular platform products may not become widely adopted and physicians may consider alternative treatments for their patients. Another significant factor that physicians will consider is acute safety data on complications that occur during the use of our Lumivascular platform products. If the results obtained from any post-market studies that we conduct or post-clearance surveillance indicate that the use of our Lumivascular platform products are not as safe or effective as other treatment options or as current short-term data would suggest, adoption of our product may suffer and our business would be harmed. In addition, we are responsible for the costs associated with conducting studies to obtain safety and efficacy data. If we are unable to obtain sufficient financing, whether through our operations or from third parties, we will not be able to conduct the studies necessary to obtain long-term data regarding the safety and efficacy of our products.

Even if we believe the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. Physicians who are technically proficient participate in our clinical trials and are high-volume users of our Lumivascular platform products. Consequently, the results of our clinical trials and their experiences using our products may lead to better patient outcomes than those of physicians that are less proficient, perform fewer procedures or who use our products infrequently.

***If we or our suppliers fail to comply with the FDA's QSR, our manufacturing operations could be delayed or shut down and Lumivascular platform sales could suffer.***

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our Lumivascular platform products. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenues to decline.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health (CDPH). The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. We have undergone numerous audits, inspections, and reviews by the FDA, CDPH, and BSI, our European Notified Body, in the past, some of which resulted in the identification of instances of non-compliance which we were required to correct. We expect that we will undergo additional audits, inspections, and reviews in the future, which could result in further corrective actions.

We can provide no assurance that we will continue to remain in substantial compliance with the QSR. If the FDA, CDPH or BSI inspect our facility and discover major compliance problems, we may have to shut down our facility and cease manufacturing until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility, we may be unable to produce our Lumivascular platform products, which would harm our business.

***Our Lumivascular platform products may in the future be subject to product recalls that could harm our reputation.***

FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our Lumivascular platform products or products we commercialize in the future would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would negatively affect our stock price.

***Changes in coverage and reimbursement for procedures using our Lumivascular platform products could affect the adoption of our Lumivascular platform and our future revenues.***

Currently, our Lumivascular platform procedure is typically reimbursed by third-party payors, including Medicare and private healthcare insurance companies, under existing reimbursement codes. These payors may change their coverage and reimbursement policies, as well as payment amounts, in a way that would prevent or limit reimbursement for our products, which would significantly harm our business. Also, healthcare reform legislation or regulation may be proposed or enacted in the future, which may adversely affect such policies and amounts. We cannot predict whether and to what extent existing coverage and reimbursement will continue to be available. If physicians, hospitals and other providers are unable to obtain adequate coverage and reimbursement for procedures performed using our Lumivascular platform products, they are significantly less likely to use our Lumivascular platform products and our business would be harmed.

***Healthcare reform measures could hinder or prevent our planned products' commercial success.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The current presidential administration and Congress may continue to attempt broad sweeping changes to the current healthcare laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

***If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.***

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to many healthcare fraud and abuse and patient privacy regulations by both the federal government and the states in which we conduct our business. The regulations that affect how we operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the HHS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the HITECH Act, which protects the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.***

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the safe storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances, such as isopropyl alcohol and other solvents. In addition, our research and development may acquire biological waste materials, such as human and animal tissue, for the sole use of product design testing. Upon completion of the product testing, these biological wastes are safely disposed of following all federal, state, local and foreign environmental laws and regulations. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

***The use, misuse or off-label use of the products in our Lumivascular platform may result in injuries that lead to product liability suits, which could be costly to our business.***

We require limited training in the use of our Lumivascular platform products because we market primarily to physicians who are experienced in the interventional techniques required to use our device. If demand for our Lumivascular platform continues to grow, less experienced physicians will likely use the devices, potentially leading to more injury and an increased risk of product liability claims. The use or misuse of our Lumivascular platform products has in the past resulted, and may in the future result, in complications, including damage to the treated artery, infection, internal bleeding, and limb loss, potentially leading to product liability claims. Our Lumivascular platform products are contraindicated for use in the carotid, cerebral, iliac, or renal arteries. Our sales force does not promote the use of our products for off-label indications, and our U.S. instructions for use specify that our Lumivascular platform products are not intended for use in the carotid, cerebral, coronary, iliac or renal arteries. However, we cannot prevent a physician from using our Lumivascular platform products for these off-label applications. The application of our Lumivascular platform products to coronary arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences. For example, if excised plaque were not captured properly in our device, it could be carried by the bloodstream to a narrower location, blocking a coronary artery, leading to a heart attack, or blocking an artery to the brain, leading to a stroke. If our Lumivascular platform products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us.

***The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our Lumivascular platform products.***

We may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses, and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operations and use of our Lumivascular platform products. Medical malpractice carriers are also withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our Lumivascular platform products and potential customers may opt against purchasing our Lumivascular platform products due to the cost or inability to procure insurance coverage.

**Risks Related to Our Organizational Structure**

***Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price has fluctuated significantly since our IPO and is likely to continue to fluctuate substantially. As a result of this price fluctuation, investors may experience losses on their investments in our stock. In addition, the development stage of our operations may make it difficult for investors to evaluate the success of our business to date and to assess our future viability. The market price for our common stock may be influenced by many factors, including:

- sales of stock by our existing stockholders, including our affiliates;
- market acceptance of our Lumivascular platform and products;
- the results of our clinical trials;
- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' and our own estimates;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- actual or anticipated fluctuations in our financial condition and operating results;
- quarterly variations in our or our competitors' results of operations;

- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation of our business;
- lawsuits threatened or filed against us;
- the announcement or approvals of new products or product enhancements by us or our competitors;
- announcements related to patents issued to us or our competitors and to litigation; and
- developments in our industry.

From time to time, our affiliates may sell stock for reasons due to their personal financial circumstances. These sales may be interpreted by other stockholders as an indication of our performance and result in subsequent sales of our stock that have the effect of creating downward pressure on the market price of our common stock. In addition, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies.

The market price and trading volume of our common stock has been volatile over the past year, and it may continue to be volatile. Over the past year, our common stock has traded as low as $9.00 and as high as $46.00 per share. We cannot predict the price at which our common stock will trade in the future and it may decline. The price at which our common stock trades may fluctuate significantly and may be influenced by many factors, including our financial results; developments generally affecting our industry; general economic, industry and market conditions; the depth and liquidity of the market for our common stock; investor perceptions of our business; reports by industry analysts; announcements by other market participants, including, among others, investors, our competitors, and our customers; regulatory action affecting our business; and the impact of other “Risk Factors” discussed in this Annual Report. In addition, changes in the trading price of our common stock may be inconsistent with our operating results and outlook. The volatility of the market price of our common stock may adversely affect investors’ ability to purchase or sell shares of our common stock.

***We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which would cause our stock price to decline.***

We have provided in the past and may provide guidance in the future about our business and future operating results. In developing this guidance, our management must make certain assumptions and judgments about our future performance, including projected revenues and the timing of regulatory approvals. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of our common stock would decline.

***If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. The analysts who previously published research reports on our stock following our IPO have discontinued coverage. Although one new analyst initiated coverage of our business in September 2019, if additional analysts do not begin regularly publishing reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

We will need to raise additional funds through future equity or debt financings to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given our stock price, any financing that we undertake in the future could cause substantial dilution to our existing stockholders.

On March 7, 2019, we filed a universal shelf registration statement (the "Shelf Registration Statement") to offer up to $50.0 million of our securities, which expires on March 29, 2022. We have established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. Due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, we are limited in our ability to use the Shelf Registration Statement.

Our directors and employees may sell our stock through 10b5-1 trading plans or in the market during open windows under our insider trading policy without such plans in place. Sales of our common stock by our directors and employees could be perceived negatively by investors or cause downward pressure on our common stock and cause a reduction in the price of our common stock as a result. We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance.

***The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.***

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities laws, rules and regulations. Compliance with these laws, rules and regulations have increased our legal and financial compliance costs and will make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company." The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. Our management and other personnel now need to devote a substantial amount of time to these compliance initiatives. As a result, management's attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We will incur additional compensation costs in the event that we decide to pay our executive officers cash compensation closer to that of executive officers of other public medical device companies, which would increase our general and administrative expense and could harm our profitability. Any future equity awards will also increase our compensation expense. We also expect that being a public company and compliance with applicable rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee.

As a result of disclosure of information in this Annual Report on Form 10-K and in other filings required of a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

***Nasdaq may delist our securities from its exchange, which could harm our business and limit our stockholders' liquidity.***

Our common stock is currently listed on the Nasdaq Capital Market ("Nasdaq"), which has qualitative and quantitative listing criteria. However, we cannot assure you that our common stock will continue to be listed on Nasdaq in the future. In order to continue listing our common stock on Nasdaq, we must maintain certain financial, distribution and stock price levels. Generally, we must maintain a minimum amount in stockholders' equity, a minimum number of holders of our common stock and a minimum bid price.

On September 22, 2021, we received a letter from Nasdaq's Listing Qualifications Department notifying us that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price for our listed securities was less than $1 for the previous 30 consecutive business days. We had a period of 180 calendar days, or until March 21, 2022, to regain compliance with the rule referred to in this paragraph. To regain compliance, the bid price of our common stock must close at $1 or more for a minimum of ten consecutive business days. The notice has no present impact on the listing of our securities on Nasdaq. On March 14, 2022, we effected a 1-for-20 reverse stock split of our outstanding shares of common stock. However, there is no guarantee that such reverse stock split will result in the bid price of our common stock closing at $1 or more for the required ten consecutive business days.

We have not yet regained compliance with the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have provided written notice to Nasdaq requesting an additional 180 calendar days to cure the deficiency on March 17, 2022, but have not yet received a response.

In the event that we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the compliance period, we will receive written notification that our securities are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. We intend to actively monitor our bid price and will consider available options to resolve the deficiency and regain compliance with the Nasdaq Listing Rules, including considering whether to conduct a reverse stock split.

If Nasdaq delists our common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." If our common stock continues to be listed on NASDAQ, our common stock will be a covered security. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case.

***Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could discourage a takeover.***

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;
- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholder's notice;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- allowing stockholders to remove directors only for cause;
- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- limiting the forum for certain litigation against us to Delaware; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders, (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law or our certificate of incorporation or bylaws (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws, or (v) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers or employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We have not paid cash dividends in the past and do not expect to pay cash dividends in the future, and any return on investment may be limited to the value of our stock.***

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. In addition, our Loan Agreement with CRG prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. The terms of our Series A preferred stock, Series B preferred stock and Series D preferred stock provide that we may not pay dividends on our common stock without concurrently declaring dividends on each. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if you sell our common stock after our stock price appreciates. For more information on restrictions governing our ability to pay dividends, see the section titled "*Dividend Policy*" below.

***CRG has the ability to exert significant control over matters pursuant to the protective provisions therein as well as the covenants and other restrictions in the Loan Agreement.***

Even though Series A preferred stock is non-voting stock, our governing documents, as amended, have protective provisions that will require CRG to consent to certain significant Company events. For example, CRG's consent would be necessary to create additional shares of Series A preferred stock, amend our organizational documents, or approve any merger, sale of assets, or other major corporate transaction. This consent requirement could delay or prevent any acquisition of our company on terms that other stockholders may desire, and may adversely affect the market price of our common stock.

***The Series A preferred stock and Series D preferred stock have a liquidation preference senior to our common stock and Series B preferred stock.***

Series A preferred stock and Series D preferred stock have a liquidation preference that gets paid prior to any payment on our common stock (including shares issuable upon the exercise of our outstanding warrants) and Series B preferred stock. As a result, if we were to dissolve, liquidate, merge with another company or sell our assets, the holders of our Series A preferred stock would have the right to receive up to approximately $56.4 million as of December 31, 2021, plus any unpaid dividends, and, after the payment of the liquidation preference to the holders of the Series A preferred stock before any amount is paid to the holders of our Series B preferred stock or common stock or pursuant to the redemption rights in the warrants for fundamental transactions. The holders of our Series D preferred stock would also have the right to receive up to $0.01 per share of Series D preferred stock, subject to the liquidation preference of the Series A preferred stock. The payment of the liquidation preferences could result in common stockholders, Series B preferred stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily. In January 2019, December 2019, December 2020 and December 2021, 2,945, 3,580, 3,866 and 4,175 additional shares of Series A preferred stock, respectively, were issued to CRG as payment of dividends accrued through December 31, 2021.

The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control.

***We depend on our board of directors and the loss of one or more or our board members or an inability to attract and retain highly qualified members could harm our business.***

Our success largely depends upon the continued services and involvement of the members of our board of directors and the loss of one or more of our directors could adversely affect us. Additionally, changes in the composition of our board resulting from the addition or departure of members could disrupt our business.

We must attract and retain highly qualified board members. Competition for these individuals can be intense. We have, from time to time, experienced, and we may experience in the future, difficulty in adding and retaining members of our board with appropriate qualifications. In addition, some states and other regulatory authorities, including Nasdaq, have adopted board diversity requirements, which mandate that companies have a minimum number of directors who meet specified diversity criteria, or otherwise require that companies disclose board diversity information. If we are unable to attract and retain qualified board members who meet such diversity criteria, we will be unable to comply with such requirements and could face enforcement or other regulatory actions.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease located in Redwood City, California. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 842, *Leases*, using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments.

The lease will expire on November 30, 2024. The Company is obligated to pay approximately $5.8 million in base rent payments through November 2024, beginning on December 1, 2019. The weighted average remaining lease term as of December 31, 2021 is 2.9 years.

We believe that our current facilities are adequate for our current and anticipated future needs through at least 2022.

## ITEM 3. LEGAL PROCEEDINGS

We are not involved in any pending legal proceedings that we believe could have a material adverse effect on our financial condition, results of operations or cash flows. From time to time we may be involved in legal proceedings or investigations, which could harm our reputation, business and financial condition and divert the attention of our management from the operation of our business.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock began trading on the Nasdaq Global Market on January 30, 2015 and was transferred to the Nasdaq Capital Market on January 19, 2018, where it trades under the symbol "AVGR".

### HOLDERS OF RECORD

As of March 18, 2022, there were 5,428,770 shares of our common stock held by 123 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

### DIVIDEND POLICY

Our Series A preferred stock carries an 8% cumulative dividend, which accumulates and is compounded annually. This cumulative dividend is payable in arrears on December 31 of each year, commencing with December 31, 2018, and at our option is payable in additional shares of Series A preferred stock. Additionally, the terms of our Series A preferred stock and Series B preferred stock provide that we may not declare dividends on the common stock without concurrently declaring dividends on such series of preferred stock in an amount equal to that payable had they been converted to common stock prior to the dividend. We have issued a total of 14,566 shares of Series A preferred stock to pay the preferred dividend to the holder of Series A preferred stock through December 31, 2021. Other than the preferred dividend on Series A preferred stock, we have never declared or paid any cash dividends on any of our capital stock. Except with respect to the Series A preferred stock's cumulative dividend, we do not anticipate paying any dividends in the foreseeable future and currently intend to retain all available funds and any future earnings for use in the operation of our business and to finance the growth and development of our business.

Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our Loan Agreement with CRG prohibits us from paying any dividends or making any other distribution or payment on account of our common stock.

### RECENT SALES OF UNREGISTERED SECURITIES

There were no sales of unregistered securities during fiscal 2021 other than those transactions previously reported to the SEC on a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

### PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

### ITEM 6. [RESERVED]

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Annual Report on Form 10-K entitled "Risk factors.*"

### Overview

We are a commercial-stage medical device company that designs, manufactures and sells real-time image-guided, minimally invasive catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular real-time image-guided system available in this market.

We design, manufacture, and sell a suite of products in the United States and select international markets. We are located in Redwood City, California. Our current Lumivascular platform consists of products including our Lightbox real-time imaging console, the Ocelot family of catheters, which are image-guided catheters designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and the Pantheris family of catheters, our image-guided atherectomy family of catheters which is designed to allow physicians to precisely remove arterial plaque in PAD patients.

We received CE Marking for our original Ocelot product in September 2011 and received from the U.S. Food and Drug Administration, or FDA, 510(k) clearance in November 2012. We received 510(k) clearance from the FDA for commercialization of Pantheris in October 2015. We received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select European countries promptly thereafter. In May 2018, we received 510(k) clearance from the FDA for our current next-generation version of Pantheris. In April 2019, we received 510(k) clearance from the FDA for our Pantheris SV, a version of Pantheris targeting smaller vessels, and commenced sales in July 2019. In September 2020, we received 510(k) clearance of Tigereye, a next-generation CTO crossing system utilizing Avinger's proprietary image-guided technology platform. Tigereye is a product line extension of Avinger's Ocelot family of image-guided CTO crossing catheters. In January 2022, we received 510(k) clearance from the FDA for our Lightbox 3 imaging console, a version of our Lightbox presenting significant reductions in size, weight and cost in comparison to the incumbent version.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain, and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments for PAD include stenting, angioplasty, and atherectomy, which is the use of a catheter-based device for the removal of plaque. These treatments all have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which is referred to as the external elastic lamina, or EEL.

We believe our Lumivascular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment through the use of optical coherence tomography, or OCT, a high resolution, light-based, radiation-free imaging technology. Our Lumivascular platform provides physicians with real-time OCT images from the inside of an artery, and we believe Ocelot and Pantheris are the first products to offer intravascular visualization during CTO crossing and atherectomy, respectively. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our Lumivascular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding damage to healthy portions of the artery.

During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support our August 2015 510(k) submission to the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and efficacy endpoints. We believe the data from VISION allows us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the external elastic lamina, which is the membrane between the outermost layers of the artery, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. Although the original VISION study protocol was not designed to follow patients beyond six months, we worked with 18 of the VISION sites to re-solicit consent from previous clinical trial patients in order for them to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the remaining patients from participating sites was completed in May 2017, and we released the final 12- and 24-month results for a total of 89 patients in July 2017.

During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a submission to the FDA to expand the indication for our Pantheris atherectomy device to include in-stent restenosis. Patient enrollment began in October 2017 and was completed in July 2021. Patient outcomes are being evaluated at thirty days, six months and one year following treatment. In November 2021, we received 510(k) clearance from the FDA for a new clinical indication for treating in-stent restenosis with Pantheris using the data collected and analyzed from INSIGHT. We expect this will expand our addressable market for Pantheris to include a high-incidence disease state for which there are few available indicated treatment options.

We focus our direct sales force, marketing efforts and promotional activities on interventional cardiologists, vascular surgeons and interventional radiologists. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. Although our sales and marketing efforts are directed at these physicians because they are the primary users of our technology, we consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products. We are designing additional future products to be compatible with our Lumivascular platform, which we expect to enhance the value proposition for hospitals to invest in our technology. Pantheris qualifies for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our products.

We have assembled a team with extensive medical device development and commercialization experience in both start-up and large, multi-national medical device companies. We assemble all of our products at our manufacturing facility but certain critical processes, such as coating and sterilization, are performed by outside vendors. We expect our current manufacturing facility in California, will be sufficient through at least 2022. We generated revenues of $9.1 million in 2019 and $8.8 million in 2020 and $10.1 million in 2021. The decline in revenue in 2020 was primarily due to the adverse effects of COVID-19 on our customers as hospitals deferred elective procedures.

**Recent Developments**

*COVID-19 Update*

As a result of the effects of the COVID-19 pandemic, we experienced a significant decline in sales in the second quarter of 2020, particularly as individuals, as well as hospitals and other medical providers, deferred elective procedures in response to COVID-19. Starting in the third quarter of 2020, we experienced a rebound of sales as practitioners began to once again perform elective procedures. At present, a majority of jurisdictions have eased or are in the process of lifting restrictions on performing elective procedures, we cannot be certain that other jurisdictions in the United States will do so in the near future. Some jurisdictions have experienced and continue to experience a resurgence in COVID-19 cases, which has prompted certain hospitals and other medical providers in such areas to again defer elective procedures or further prolong or reinstate existing restrictions on such procedures. If other jurisdictions experience a resurgence in COVID-19 cases, these jurisdictions may also prolong restrictions on elective procedures. This situation has created a significant amount of volatility in the medical industry which makes future developments and results difficult to predict. While sales during 2021 increased in comparison to 2020, we believe COVID-19 has had and will continue to have an adverse effect on our ability to generate sales due to the fluctuating and unpredictable levels of capacity medical providers have to perform procedures that require the use of our products. Consequently, it is unclear whether any reduction in sales from levels experienced prior to COVID-19 is temporary and whether such sales may be recoverable in the future. In addition, we have experienced disruptions in our manufacturing and supply chain, as well as delays in site initiation and patient enrollment for our clinical studies. If we are unable to successfully complete these or other clinical studies, our business and results of operations could be harmed.

During 2020, we undertook actions to manage our available cash and other resources to help mitigate the effects of COVID-19 on our business, including by adjusting production to match demand for our products and reducing discretionary costs. For example, during the second quarter of 2020, we reduced base salaries for all of our non-manufacturing employees by 20% and reduction of hours worked by our manufacturing workers by 20%. Salaries and hours worked returned to prior levels starting in the third quarter of 2020. However, the COVID-19 pandemic and responses thereto have resulted in reduced consumer and investor confidence, instability in the credit and financial markets, volatile corporate profits, and reduced business and consumer spending, which could increase the cost of capital and/or limit the availability of capital to us in the future. These and other factors could adversely affect our ability to effectively manage our available cash and other resources.

*Nasdaq Delisting Notice*

On September 22, 2021, we received a letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"), as the minimum bid price for the Company's listed securities was less than $1.00 for the previous 30 consecutive business days. We had a period of 180 calendar days, or until March 21, 2022, to regain compliance with the rule referred to in this paragraph. To regain compliance, the bid price of our common stock must close at $1 or more for a minimum of ten consecutive business days. The notice has no present impact on the listing of our securities on Nasdaq. On March 14, 2022, we effected a 1-for-20 reverse stock split of our outstanding shares of common stock. However, there is no guarantee that such reverse stock split will result in the bid price of our common stock closing at $1 or more for the required ten consecutive business days.

We have not yet regained compliance with the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we provided written notice to Nasdaq requesting an additional 180 calendar days to cure the deficiency on March 17, 2022, but have not yet received a response.

In the event that we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the compliance period, we will receive written notification that its securities are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. We intend to actively monitor the bid price of our common stock and will consider available options to resolve the deficiency and regain compliance with the Nasdaq Listing Rules, including conducting a reverse stock split.

*Global Supply Chain*

We are closely monitoring the impacts of COVID-19 and general economic conditions on global supply chain, manufacturing, and logistics operations. As inflationary pressures increase, we anticipate that our production and operating costs may similarly increase, including costs and availability of materials and labor. In addition, COVID-19 and other events, including port closures or labor shortages, have resulted in manufacturing and shipping constraints generally. While we have had sufficient inventory on-hand to meet our production requirements and customer demand, we have experienced some constraints with respect to the availability of certain materials and extended lead times from certain key suppliers. We have also experienced some delays in shipping products to our customers. Any significant delay or interruption in our supply chain could impair our ability to meet the demands of our customers and could harm our business.

*Reverse Stock Split*

On March 11, 2022, our Board of Directors approved an amendment to our amended and restated certificate of incorporation to effect a 1-for-20 reverse stock split of our issued and outstanding common stock. The reverse stock split became effective on March 14, 2022. The par value of the common stock and preferred stock was not adjusted as a result of the reverse stock split. All common stock, stock options, and restricted stock units, and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock splits.

**Financing**

During the years ended December 31, 2021 and 2020, our net loss and comprehensive loss was $17.4 million and $19.0 million, respectively. We have not been profitable since inception, and as of December 31, 2021, our accumulated deficit was $384.8 million. Since inception, we have financed our operations primarily through private and public placements of our preferred and common securities and, to a lesser extent, debt financing arrangements.

In September 2015, we entered into a Term Loan Agreement, or Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively CRG, under which we were able to borrow up to $50.0 million on or before March 29, 2017, subject to certain terms and conditions. We borrowed $30.0 million on September 22, 2015 and an additional $10.0 million on June 15, 2016 under the Loan Agreement. Contemporaneously with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 44 shares of our common stock on September 22, 2015 at a price of $111,928 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the Securities Purchase Agreement, we filed a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect.

On February 14, 2018, we entered into a Series A preferred stock Purchase Agreement (the "Series A Purchase Agreement") with CRG, pursuant to which it agreed to convert $38.0 million of the outstanding principal amount of its senior secured term loan (plus the back-end fee and prepayment premium applicable thereto) under the Loan Agreement into a newly authorized Series A preferred stock. As discussed in the section of this report titled "Dividend Policy," the holders of Series A preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at our option. The shares of Series A preferred stock have no voting rights and rank senior to all other classes and series of the Company's equity in terms of repayment and certain other rights.

We have entered into several amendments to the Term Loan Agreement (the "Amendments") with CRG since September 2015, the most recent of which, was entered into on January 22, 2021. The Amendments, among other things: (1) extended the interest-only period through December 31, 2023; (2) extended the period during which we may elect to pay a portion of interest in payment-in-kind, or PIK, interest payments through December 31, 2023 so long as no default has occurred and is continuing; (3) permitted us to make our entire interest payments in PIK interest payments for through December 31, 2023 so long as no default has occurred and is continuing; (4) extended the maturity date to December 31, 2025; (5) reduced the minimum liquidity requirement to $3.5 million at all times; (6) eliminated the minimum revenue covenant for 2018, 2019 and 2020; (7) reduced the minimum revenue covenant to $8 million for 2021, $10 million for 2022; (8) added minimum revenue covenants for of $12 million for 2023, $14.5 million for 2024 and $17 million for 2025; (9) changed the date under the on-going stand-alone representation regarding no "Material Adverse Change" to December 31, 2020; (10) amended the on-going stand-alone representation and stand-alone event of default regarding Material Adverse Change such that any adverse change in or effect upon the revenue of us and our subsidiaries due to the outbreak of COVID-19 will not constitute a Material Adverse Change; and (11) provided CRG with board observer rights.

**Components of our Results of Operations**

***Revenues***

All of our revenues are currently derived from sales of our various PAD catheters in the United States and select international markets, Lightbox consoles, and related services. We expect our revenues to increase in 2022 due to the availability of our Tigereye product launch in late 2020 and easing of restrictions on elective procedures due to the diminishing impact of COVID-19. For the year ended December 31, 2021, there was one customer that represented 10% of revenues. For the year ended December 31, 2020, there were no customers that represented 10% or more of revenues.

Revenues may fluctuate from quarter to quarter due to a variety of factors including capital equipment purchasing patterns that are typically increased towards the end of the calendar year and decreased in the first quarter. In addition, during the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients. Additionally, we believe COVID-19 has had and will continue to have an adverse effect on our ability to generate sales due to the fluctuating and unpredictable levels of capacity medical providers have to perform procedures that require the use of our products.

***Cost of Revenues and Gross Margin***

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. We expense all warranty costs and inventory provisions as cost of revenues. We periodically write-down inventory for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. A significant portion of our cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases. Cost of revenues also includes depreciation expense for production equipment, depreciation and related maintenance expense for placed Lightboxes held by customers and certain direct costs such as those incurred for shipping our products.

We calculate gross margin as gross profit divided by revenues. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, manufacturing costs, product yields, headcount, charges for excess and obsolete inventories and cost-reduction strategies. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. In the future, we may seek to manufacture certain of our products outside the United States to further reduce costs. Our gross margin will likely fluctuate from quarter to quarter as we continue to introduce new products and sales channels, and as we adopt new manufacturing processes and technologies.

***Research and Development Expenses***

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical and regulatory affairs, consulting services, materials, depreciation and other costs associated with products and technologies in development. These expenses include employee compensation, including stock-based compensation, supplies, materials, quality assurance expenses allocated to R&D programs, consulting, related travel expenses and facilities expenses. Clinical expenses include clinical trial design, clinical site reimbursement, data management, travel expenses and the cost of manufacturing products for clinical trials. We expect R&D expenses to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

***Selling, General and Administrative Expenses***

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, selling and marketing functions, physician education programs, business development, finance, information technology and human resource functions. Other SG&A expenses include commissions, training, travel expenses, educational and promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs and general corporate expenses. We expect SG&A expenses to increase as we expand our commercial efforts.

***Interest Expense, net***

Interest expense, net consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our various debt agreements.

***Other Income, net***

Other income, net primarily consists of gains and losses resulting from the remeasurement of foreign exchange transactions and other miscellaneous income and expenses.

**Results of Operations (in thousands):**

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Revenues | $ 10,130 | $ 8,761 |
| Cost of revenues | 6,706 | 6,143 |
| Gross profit | 3,424 | 2,618 |
| Gross margin | 34% | 30% |
| | | |
| Operating expenses: | | |
| Research and development | 5,900 | 5,695 |
| Selling, general and administrative | 15,625 | 14,327 |
| Total operating expenses | 21,525 | 20,022 |
| Loss from operations | (18,101) | (17,404) |
| Interest expense, net | (1,648) | (1,658) |
| Other income, net | 2,337 | 56 |
| Net loss and comprehensive loss | $ (17,412) | $ (19,006) |

***Comparison of Years Ended December 31, 2021 and 2020***

*Revenues.*

Revenues increased $1.4 million, or 16%, to $10.1 million during the year ended December 31, 2021. The increased revenues reflect the impact of the commercial release of our Tigereye product in January 2021 and the rebounding of sales from COVID-19 as practitioners once again started to perform elective surgical procedures in certain jurisdictions. As mentioned previously, we have experienced fluctuating demand resulting from uncertainties due to the impact of COVID-19 on capacity limitations in hospitals. However, the capacity limitations experienced during the year ended December 31, 2021 were not as pervasive, and haven't had as profound an impact on revenues, in comparison to the prior fiscal year. We anticipate that COVID-19 could continue to impact hospital capacities, and related demand for our products, for the foreseeable future.

*Cost of Revenues and Gross Margin.*

Cost of revenues increased $0.6 million, or 9%, to $6.7 million during the year ended December 31, 2021. This increase was primarily attributable to the increase in revenues. Stock-based compensation expense within cost of revenues totaled $0.1 million for each of the years ended December 31, 2021 and 2020.

Gross margin for the year ended December 31, 2021 increased to 34% compared to 30% in the prior year. The increase in gross margin was primarily due to the rebound of revenues from the significant decline experienced during the three months ended June 30, 2020 due to COVID-19 and the economies of scale experienced in 2021 relating to increased levels of production.

*Research and Development Expenses.*

R&D expenses increased $0.2 million or 4%, to $5.9 million during the year ended December 31, 2021. The increase is primarily due to increases in compensation expense resulting from the cessation of cost reduction measures taken due to COVID-19 in the third quarter of 2020 and higher project spending for next generation products such as Lightbox 3. Stock-based compensation expense within R&D totaled $0.3 million and $0.5 million for the years ended December 31, 2021 and 2020, respectively. We expect R&D expense to remain flat.

*Selling, General and Administrative Expenses.*

SG&A expenses increased $1.3 million, or 9%, to $15.6 million during the year ended December 31, 2021. This increase was primarily due to increases in compensation expense resulting from the cessation of cost reduction measures taken due to COVID-19 in the third quarter of 2020 and increased variable compensation resulting from the rebounding of sales as practitioners have once again started to perform elective surgical procedures. Stock-based compensation expense within SG&A totaled $0.6 million and $0.9 million for the years ended December 31, 2021 and 2020, respectively.

*Interest Expense, net.*

Interest expense, net is comprised of interest expense net of interest income. Interest expense remained flat compared to the prior year primarily due to the amendment of the CRG loan, pursuant to which we extended the maturity date of the loan thereby resulting in lesser interest expense in the near term. This was partially offset by lower interest income as compared to the prior year, due to the decline in money market interest rates during the period.

*Other income, net.*

Other income, net primarily consists of gains and losses resulting from the remeasurement of foreign exchange transactions and other miscellaneous income and expenses. Other income, net for the year ended December 31, 2021 increased $2.3 million in comparison to the prior year as the PPP loan was fully forgiven resulting in a gain on extinguishment of that debt. Both periods included remeasurement gains and losses from foreign exchange transactions which are typically a small percentage of transaction volume, usually resulting in nominal changes between periods.

**Liquidity and Capital Resources**

As of December 31, 2021, we had cash and cash equivalents of $19.5 million and an accumulated deficit of $384.8 million, compared to cash and cash equivalents of $22.2 million and an accumulated deficit of $367.3 million as of December 31, 2020. We expect to incur losses for the foreseeable future. We believe that our cash and cash equivalents of $19.5 million at December 31, 2021, together with the approximately $6.7 million net proceeds from the January 2022 equity financing (see Equity Financings below), expected revenues, debt and financing activities and funds from operations will be sufficient to allow us to fund our current operations through the second quarter of 2023.

To date, we have financed our operations primarily through net proceeds from the issuance of our preferred stock and debt financings, our “at-the-market” program, our initial public offering, or IPO, our follow-on public offerings and warrant issuances. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which divert resources from other activities. Additional financing may not be available at all, or if available, may not be in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and we may be required to significantly scale back our business and operations.

In addition, the COVID-19 pandemic and responses thereto have resulted in reduced consumer and investor confidence, instability in the credit and financial markets, volatile corporate profits, restrictions on elective medical procedures, and reduced business and consumer spending, which could increase the cost of capital and/or limit the availability of capital to us. While we have taken certain actions to manage our available cash and other resources to mitigate the effects of COVID-19 on our business, there can be no assurance that such strategies will be successful in mitigating the negative impacts of the COVID-19 pandemic on our liquidity and capital resources.

*Equity Financings*

On January 31, 2020, we completed a public offering of 321,429 shares of common stock at an offering price of $14.00 per share. As a result, we received net proceeds of approximately $3.9 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to $14.00 per share.

On April 30, 2020, we completed a public offering of 630,000 shares of common stock at an offering price of $5.00 per share. On May 6, 2020, we issued an additional 94,500 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter’s over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately $3.0 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to $5.00 per share.

On June 26, 2020, we completed a public offering of 1,000,000 shares of common stock at an offering price of $5.40 per share. On July 9, 2020, we issued an additional 150,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter’s over-allotment option in connection with the aforementioned offering resulting in $0.7 million of additional net proceeds. As a result, we received aggregate net proceeds of approximately $5.5 million including the overallotment option and after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 6, 2020, under our universal shelf registration statement filed on March 7, 2019 (the "Shelf Registration Statement,"), we completed a public offering of 789,474 shares of common stock at an offering price of $7.60 per share. On August 11, 2020, we issued an additional 118,421 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately $6.2 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 25, 2020, under the Shelf Registration Statement, we completed a public offering of 553,192 shares of common stock at an offering price of $9.40 per share. On September 1, 2020, we issued an additional 50,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately $5.1 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On February 2, 2021, under the Shelf Registration Statement, we completed a bought deal offering of 500,000 shares of common stock at an offering price of $28.80 per share. As a result, we received aggregate net proceeds of approximately $13.0 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

*January 2022 Offering*

On January 14, 2022, the Company entered into a securities purchase agreement with several institutional investors pursuant to which the Company agreed to sell and issue, in a registered direct offering ("January 2022 offering"), an aggregate of 7,600 shares of the Company's Series D Convertible Preferred Stock, par value of $0.001 per share, at an offering price of $1,000 per share. Concurrently, the Company agreed to issue to these investors warrants to purchase up to an aggregate of 807,500 shares of the Company's common stock (the "Common Warrants"). As a result, the Company received aggregate net proceeds of approximately $6.7 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

In connection with the January 2022 offering and in accordance with the securities purchase agreement, we held a special meeting of stockholders on March 11, 2022 to consider a proposal (the "Proposal") to amend to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Charter") to effect a reverse split of the outstanding shares of the Company's common stock at a ratio between 1-for-5 and 1-for-20 (the "Reverse Split Amendment"). Our stockholders approved the Reverse Split Amendment at the special meeting. On March 11, 2022, following receipt of stockholder approval, our Board of Directors approved a reverse split ratio of 1-for-20 and we filed an amendment to our Charter to effect such reverse stock split, effective as of 5:00 pm Eastern Time on March 14, 2022.

Pursuant to the purchase agreement, the Company filed a certificate of designation (the "Certificate of Designation") with the Secretary of State of Delaware designating the rights, preferences and limitations of the shares of Series D preferred stock, which became effective on January 14, 2022. The Certificate of Designation provided, in particular, that the Series D preferred stock will have no voting rights, other than the right to vote as a class on certain matters, except that each share of Series D preferred stock had the right to cast 37,500 votes per share of Series D preferred stock on the Proposal (the "Supermajority Voting Rights"); provided, that the votes cast by the holders of the Series D preferred stock must be counted in the same proportion as the aggregate shares of common stock voted on the Proposal. Because the Proposal was approved by our stockholders at the special meeting held on March 11, 2022, the Series D preferred stock no longer has Supermajority Voting Rights.

The holders of the Series D preferred stock are entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Series D preferred stock is convertible into shares of common stock at a conversion price of $8.00 per share, as adjusted for the most recent reverse stock split. The conversion price can be adjusted pursuant to the Certificate of Designation for stock dividends and stock splits, subsequent rights offerings, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the Certificate of Designation). The Series D preferred stock can be converted at the option of the holders at any time. In addition, subject to the satisfaction of certain conditions, we may cause the holders of the Series D preferred stock to convert their shares of Series D preferred stock; provided, that shares of Series D preferred stock cannot be converted to common stock if the applicable holder would beneficially own in excess of 4.99% (or, upon election by such holder prior to the issuance of any shares of Series D preferred stock, 9.99%) of our outstanding common stock. A holder of Series D preferred stock may, upon notice to us, increase or decrease such beneficial ownership limitation, but not in excess of 9.99%. In March 2022, after the effectiveness of the Reverse Split Amendment, 5,200 shares of Series D preferred stock were converted into an aggregate of 650,000 shares of common stock.

The Common Warrants have an exercise price of $9.60 per share and become exercisable beginning July 14, 2022. The Common Warrants will expire five years following the time they become exercisable, or July 14, 2027. The Company also issued to the Placement Agent or its designees warrants to purchase up to an aggregate of 66,500 shares of common stock (the "Placement Agent Warrants"). The Placement Agent Warrants are subject to the same terms as the Common Warrants, except that the Placement Agent Warrants have an exercise price of $10.00 per share and a term of five years from the commencement of the sales pursuant to the January 2022 Offering, or January 12, 2027.

As a result of the issuance of the Common Warrants and Placement Agent Warrants issued in connection with our January 2022 offering, we expect a significant non-cash charge which will reduce our net income in the first quarter of 2022.

*PPP Loan*

On April 23, 2020, the Company received loan proceeds of $2.3 million (the "PPP Loan") pursuant to the PPP under the CARES Act. The PPP Loan, which was in the form of a promissory note, dated April 20, 2020 (the "Promissory Note"), between the Company and Silicon Valley Bank ("SVB") as the lender, was set to mature on April 20, 2022 and bore interest at a fixed rate of 1% per annum, payable monthly commencing six months from the date of the PPP Loan. The Company may voluntarily prepay the borrowings in full with no associated penalty or premium.

As previously disclosed, the PPP was administered by the U.S. Small Business Administration (the "SBA"). The SBA was given the authority under the PPP to forgive loans if all employees were kept on the payroll for a required period and the loan proceeds were used for payroll, rent and utilities. The Company applied for debt forgiveness in December 2020.

On April 17, 2021, the Company was notified by SVB that its PPP Loan had been fully forgiven by the SBA and that there was no remaining balance on the PPP Loan. The Company recorded the forgiveness as other income in April 2021 in the amount of $2.4 million, of which approximately $23,000 was accrued interest.

**Contractual Obligations**

Our principal obligations consist of the operating lease for our facility, our Loan Agreement with CRG and non-cancelable purchase commitments. The following table sets out, as of December 31, 2021, our contractual obligations due by period (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Within 1 Year | 2 - 3 Years | 4-5 Years | More Than 5 Years | Total |
| Operating lease obligations [1] | $ 1,162 | $ 2,341 | $ — | $ — | $ 3,503 |
| CRG Loan [2] | — | 9,045 | 10,339 | — | 19,384 |
| Noncancellable purchase commitments [3] | 1,411 | 3 | 26 | — | 1,440 |
| | $ 2,573 | $ 11,389 | $ 10,365 | $ — | $ 24,327 |

(1) Operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease. In addition to the minimum future lease commitments presented above, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease will expire on November 30, 2024.
(2) The total CRG Loan amount, shown as borrowings on the balance sheet as of December 31, 2021, is $12.3 million. The contractual obligation in the table above of $19.4 million under the CRG Loan includes future interest to be accrued but not paid in cash as well as a $2.2 million back-end fee to be paid in December 2025 upon maturity of the CRG Loan which is being accreted. Refer to Item 8, Financial Statements and Supplementary Data, Footnote 7 for additional details.
(3) Noncancelable purchase commitments consist of agreements to purchase goods and services entered into in the ordinary course of business.

*CRG Loan*

On March 2, 2020, we and CRG further amended the Loan Agreement to change the date upon which cash payments for interest would commence from the first quarter of 2020 to the third quarter of 2021. No cash payments for principal would be made until the final two years of the loan, which would mature in June 2023 at the time. On May 12, 2020, we and CRG entered into another amendment to waive the requirement that we comply with the minimum required revenue covenant for 2020 and granted us the ability to optionally prepay in whole or in part the outstanding principal amount of the Loan for the Redemption Price. On January 22, 2021, we and CRG entered into yet another amendment to extend the maturity date of the Loan Agreement from June 30, 2023 to December 31, 2025 while also extending the interest only payment period and the period we can make interest payments in PIK to December 31, 2023. This amendment also established minimum revenue covenants of $12 million for 2023, $14.5 million for 2024, and $17.5 million for 2025, among other things. The total CRG Loan amount, shown as long-term borrowings on the balance sheet as of December 31, 2021, is $12.3 million. However, upon maturity of the debt in December 2025, we will be obligated to pay $19.4 million under the CRG Loan, which includes future interest to be accrued but not paid in cash as well as a $2.2 million back-end fee to be paid in December 2025 upon maturity of the CRG Loan which is being accreted to the maturity date. Refer to Item 8, Financial Statements and Supplementary Data, Footnote 7 for additional details.

*Lease Agreements*

Our operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease. In addition to the minimum future lease commitments presented below, the lease requires us to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. We record deferred rent calculated as the difference between rent expense and the cash rental payments.

The lease will expire on November 30, 2024. We are obligated to pay a total approximately $5.8 million in base rent payments through November 2024, beginning on December 1, 2019. The weighted average remaining lease term as of December 31, 2021 is 2.9 years.

**Cash Flows**

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (15,697) | $ (14,835) |
| Investing activities | (34) | 65 |
| Financing activities | 13,043 | 26,012 |
| Net (decrease) increase in cash and cash equivalents | $ (2,688) | $ 11,242 |

***Net Cash Used in Operating Activities***

Net cash used in operating activities for the year ended December 31, 2021 was $15.7 million, consisting primarily of a net loss of $17.4 million and a decrease in net operating assets of approximately $0.4 million, partially offset by net non-cash charges of $1.3 million. We recognized a non-cash gain on extinguishment of debt due to the forgiveness of the PPP Loan of $2.4 million. This gain was partially offset by non-cash charges related to stock-based compensation of $1.0 million, non-cash interest expense of $1.6 million, and depreciation of $0.7 million. The decrease in net operating assets was primarily due to an increase in accounts payable and other long-term liabilities; partially offset by the increase in inventory and a decrease in accrued compensation.

Net cash used in operating activities for the year ended December 31, 2020 was $14.8 million, consisting primarily of a net loss of $19.0 million and an increase in net operating assets of approximately $0.6 million, partially offset by non-cash charges of $4.7 million. Non-cash charges largely related to stock-based compensation of $1.5 million, non-cash interest expense and other charges of $1.5 million, depreciation and amortization of $0.9 million and provisions for excess and obsolete inventory of $0.5 million. The increase in net operating assets was primarily due to the increase in inventory and a decrease in accrued compensation.

***Net Cash (Used in) Provided by Investing Activities***

Net cash used in investing activities during the year ended December 31, 2021 of $34,000 consisted of purchases of property and equipment.

Net cash provided by investing activities during the year ended December 31, 2020 was $65,000 consisting of proceeds from the sale of property and equipment.

***Net Cash Provided by Financing Activities***

Net cash provided by financing activities in the year ended December 31, 2021 of $13.0 million relates to proceeds from the issuance of common stock in our February 2021 public offering, net of various issuance costs.

Net cash provided by financing activities in the year ended December 31, 2020 of $26.0 million primarily relates to $23.6 million of proceeds from the issuance of common stock in our public offerings, net of various issuance costs and proceeds of $2.3 million from borrowings pursuant to the PPP Loan under the CARES Act.

**Critical Accounting Policies and Estimates**

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures of contingent assets and liabilities. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 of our financial statements included in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

***Revenue Recognition***

The Company's revenues are derived from (1) sale of Lightbox consoles, (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts and maintenance. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. The Company's revenues are measured based on consideration specified in the contract with each customer, net of any sales incentives and taxes collected from customers that are remitted to government authorities. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement. The Company's revenue recognition policies generally result in revenue recognition at the following points:

1. Lightbox console sales: Provided all other criteria for revenue recognition have been met, the Company recognizes revenue for Lightbox console sales directly to end customers when delivery and acceptance occurs, which is defined as receipt by the Company of an executed form that the installation process is complete.

2. Sales of disposables: Disposable revenues consist of sales of the Company's catheters and accessories and are recognized when the product has shipped, risk of loss and title has passed to the customer and collectability is reasonably assured.

3. Service revenue: Service contract revenue consists of preventative maintenance, upgrades, and service contracts. Service contracts are recognized ratably over the term of the service period and maintenance contract revenue is recognized as work is performed. To date, service revenue has been insignificant.

The Company offers its customers the ability to purchase or lease the Lightbox console. In addition, the Company provides a Lightbox under a limited commercial evaluation program to allow accounts to install and utilize the Lightbox for a limited trial period. When a Lightbox is placed under a lease agreement or under a commercial evaluation program, the Company retains title to the equipment and it remains capitalized on its balance sheet under property and equipment. Depreciation expense on these placed Lightboxes is recorded to cost of revenues on a straight-line basis. The costs to maintain these placed Lightboxes are charged to cost of revenues as incurred.

The Company evaluates its lease and commercial evaluation program agreements and accounts for these contracts under the guidance in Accounting Standards Codification ("ASC") 842, *Leases* and ASU No. 2014 09, *Revenue from Contracts with Customers (Topic 606)*. The guidance requires arrangement consideration to be allocated between a lease deliverable and a non-lease deliverable based upon the relative selling-price of the deliverables.

The Company assessed whether the embedded lease is an operating lease or sales-type lease. Based on the Company's assessment of the guidance and given that any payments under the lease agreements are dependent upon contingent future sales, it was determined that collectability of the minimum lease payments is not reasonably predictable. Accordingly, the Company concluded the embedded lease did not meet the criteria of a sales-type lease and accounts for it as an operating lease. The Company recognizes revenue allocated to the lease as the contingent disposable product purchases are delivered and are included in revenues within the statement of operations and comprehensive loss.

For sales through distributors, the Company recognizes revenue when control of the product transfers from the Company to the distributor. The distributors are responsible for all marketing, sales, training and warranty in their respective territories. The standard terms and conditions contained in the Company's distribution agreements do not provide price protection or stock rotation rights to any of its distributors. In addition, its distributor agreements do not allow the distributor to return or exchange products, and the distributor is obligated to pay the Company upon invoice regardless of its ability to resell the product.

***Inventories***

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has expired or become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. At each balance sheet date, management evaluates inventories for excess quantities, and obsolescence. This evaluation by management includes analysis of historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions, as well as the feasibility of reworking or using excess or obsolete products or components in the production or assembly of other products that are not obsolete or for which there are not excess quantities in inventory. To the extent that management determines there are excess or obsolete inventory, management adjusts the carrying value to estimated net realizable value. When quantities on hand exceed sales forecasts, a write-down is recorded for such excess inventories along with a corresponding charge to cost of revenues. The estimate of excess quantities is subjective and primarily dependent on the estimates of future demand for a particular product. Specifically, the future demand is derived based on our historical experience, from discussion with users of our products and general market conditions. Changes in assumptions of product demand could have a significant impact on the amount of write-down recorded. Inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. We also regularly review the cost of inventories against estimated market value and record a lower of cost or market reserve for inventories that have a cost in excess of estimated market value, which could have a material impact on our gross margin and inventory balances based on additional write-downs to net realizable value or a benefit from inventories previously written down.

***Stock-Based Compensation***

Stock-based compensation for the Company includes amortization related to all stock options, restricted stock units ("RSU"), based on the grant-date estimated fair value. The Company measures the fair value of RSUs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. As allowed under ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, the Company accounts for forfeitures as they occur. There haven't been any recent grants of stock options.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

***Interest Rate Risk***

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Due to the short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our cash equivalents. We do not currently use or plan to use financial derivatives in our investment portfolio.

***Credit Risk***

As of December 31, 2021, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenues from the sale of our Lumivascular platform products to hospitals and medical centers in the United States. At December 31, 2021 and 2020, there was one customer that represented 21% and 14% of accounts receivable. For the year ended December 31, 2021, there was one customer that represented 10% of revenues. For the year ended December 31, 2020, there were no customers that represented 10% or more of revenues.

***Foreign Currency Risk***

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item appears in a separate section of this Annual Report on Form 10-K beginning on page F-1 and is incorporated herein by reference.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2021. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of December 31, 2021, our disclosure controls and procedures were effective.

### Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2021.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm on our internal control over financial reporting We are currently a non-accelerated filer and are therefore not required to provide an attestation report on our internal control over financial reporting until such time as we are an accelerated filer or large accelerated filer.

### Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Inherent Limitations on Effectiveness of Controls**

Our management, including our chief executive officer and chief financial officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**ITEM 9B. OTHER INFORMATION**

None.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

## PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

### Directors

Our business affairs are managed under the direction of our board of directors, which is currently composed of four members. Three of our directors are independent within the meaning of the listing standards of The Nasdaq Stock Market, or Nasdaq. Our board of directors is divided into three staggered classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the same class whose term is then expiring.

The following table sets forth the names, ages as of March 1, 2022 and certain other information for each of the directors with terms expiring at the 2022 annual meeting of stockholders (the "Annual Meeting") (who are also nominees for election as a director at the Annual Meeting) and for each of the continuing members of our board of directors:

| | Class | Age | Position | Director Since | Current Term Expires |
|---|---|---|---|---|---|
| **Directors** | | | | | |
| James G. Cullen(1)(2)(3) | III | 79 | Director and Chairman of the Board of Directors | 2014 | 2024 |
| Jeffrey M. Soinski | I | 59 | President, Chief Executive Officer and Director | 2014 | 2022 |
| James B. McElwee(1)(2)(3) | II | 69 | Director | 2011 | 2023 |
| Tamara N. Elias(1)(2)(3) | II | 50 | Director | 2019 | 2024 |

(1) Member of our audit committee
(2) Member of our compensation committee
(3) Member of our nominating and corporate governance committee

*Jeffrey M. Soinski* has served as our President, Chief Executive Officer and a member of our Board of Directors since December 2014. From its formation in September 2009 until the acquisition of its Unisyn business by GE Healthcare in May 2013, Mr. Soinski served as Chief Executive Officer of Medical Imaging Holdings and its primary operating company Unisyn Medical Technologies, a national provider of technology-enabled products and services to the medical imaging industry. Mr. Soinski was a Director of Medical Imaging Holdings and its remaining operating company Consensys Imaging Service from September 2009 until its sale in October 2017. Mr. Soinski served periodically as a Special Venture Partner from July 2008 to June 2013 and as a Special Investment Partner since October 2016 for Galen Partners, a leading healthcare-focused private equity firm, which included Medical Imaging Holdings as one of its portfolio companies. From 2001 until its acquisition by C.R. Bard in 2008, Mr. Soinski was President and CEO of Specialized Health Products International, a publicly-traded manufacturer and marketer of proprietary safety medical products. He served on the board of directors of Merriman Holdings, parent of Merriman Capital, a San Francisco-based investment banking and brokerage firm, from 2008 until March 2016. Mr. Soinski holds a B.A. degree from Dartmouth College.

We believe Mr. Soinski is qualified to serve as a member of our board of directors because of his extensive corporate finance and business strategy experience as well as his experience with public companies.

*James G. Cullen* has served as a member of our board of directors since December 2014, as our Lead Independent Director since January 2015 and as our Non-Executive Chairman since December 2017. During the last five years, Mr. Cullen has held board and committee positions with various companies. Mr. Cullen is currently a director of Keysight Technologies, which was spun out of Agilent Technologies, where he was previously a director. Mr. Cullen previously served as a director and chairman of the audit committee of Johnson & Johnson and as a director and member of the investment and finance committees of Prudential Financial. From 1993 to 2000, Mr. Cullen was President, Vice Chairman and Chief Operating Officer of Bell Atlantic Corporation (now Verizon). From 1989 to 1993, he was President and Chief Executive Officer of Bell Atlantic-New Jersey. Mr. Cullen holds a B.A. in Economics from Rutgers University and an M.S. in Management Science from the Massachusetts Institute of Technology.

We believe Mr. Cullen is qualified to serve as a member of our board of directors because of his extensive experience serving on the boards of public companies as well as his financial and business expertise.

*James B. McElwee* has served as a member of our board of directors since March 2011. Mr. McElwee has served as an independent venture capital investor since 2010. Mr. McElwee served as general partner of Weston Presidio, a private equity and venture capital firm, from 1992 to 2010. During his tenure as a general partner and member of the investment committee, Weston Presidio led the start up financing of JetBlue Airways and made investments in Fender Musical Instruments, The Coffee Connection, Guitar Center, Mapquest, Party City, Petzazz, RE/MAX, and others.

We believe Mr. McElwee is qualified to serve as a member of our board of directors because of his substantial corporate development and business strategy expertise gained in the venture capital industry.

*Tamara N. Elias, M.D.*, was appointed to our board of directors in December 2019. Dr. Elias currently serves as VP, Head of Global Partnerships at Merck. Previously she served as Vice President of Clinical Product Development at Aetna from February 2018 to December 2019. From 2015 to 2017, Dr. Elias was Vice President of Corporate Strategy and Business Development for the $8 billion medical segment at Becton Dickinson. From 2007-2015, Dr. Elias was a Partner with Essex Woodlands Healthcare Partners, a healthcare only growth equity firm founded in 1985. Earlier in her career, Dr. Elias was a management consultant at McKinsey, advising pharmaceutical, diagnostic and device companies in R&D, product commercialization and M&A. She currently serves on the board of REVA Medical and has also previously served on the boards of several private companies, including Millennium Pharmacy Systems (sold to PharMerica), BreatheAmerica and Influence Health (sold to Healthgrades) as well on the public company board of ATS Medical (sold to Medtronic). Dr. Elias holds degrees in Biology and Anthropology from Yale University, and an M.D. from The Johns Hopkins School of Medicine. She trained as a general surgeon at Massachusetts General Hospital.

We believe Dr. Elias is qualified to serve as a member of our board of directors because of her substantial corporate development and business strategy expertise and her experience in the healthcare industry.

**Executive Officers**

The following table identifies certain information about our executive officers as of March 1, 2022. Our executive officers are appointed by, and serve at the discretion of, our board of directors. Each of our executive officers serves at the discretion of our board of directors and holds office until his successor is duly elected and qualified or until his earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

| Name | Age | Title |
|---|---|---|
| Jeffrey M. Soinski | 59 | President, Chief Executive Officer and Director |
| Mark Weinswig | 49 | Chief Financial Officer |
| Himanshu N. Patel | 61 | Chief Technology Officer |

For a brief biography of Mr. Soinski, please see the section of this Annual Report on Form 10-K titled "*Directors*."

*Mark Weinswig* has served as our Chief Financial Officer since June 2018. Prior to joining the Company, Mr. Weinswig served as Chief Financial Officer at Aqua Metals, Inc., a Nasdaq-listed heavy metal recycling company, from August 2017 to March 2018. Mr. Weinswig has previously served as Chief Financial Officer of One Workplace, a designer and manufacturer of customized workspaces, from July 2016 to July 2017. From October 2010 to June 2016, Mr. Weinswig served as Chief Financial Officer of Emcore Corporation, a Nasdaq-listed designer and manufacturer of indium phosphide optical chips, components, subsystems and systems for the broadband and specialty fiber optics market. Earlier in his career Mr. Weinswig worked at Coherent, Inc., Avanex Corporation, which merged with Bookham Technology, Morgan Stanley and PricewaterhouseCoopers. He received an M.B.A. from the University of Santa Clara and a B.S. in business administration with an accounting major from Indiana University. He has earned the CFA and CPA designations.

*Himanshu N. Patel*. co-founded Avinger in 2007 and has served as our Chief Technology Officer from January 2011 to November 2011 and since October 2013. From September 1999 to February 2007, Mr. Patel held various research and development positions, including Director of Advanced Technologies, at FoxHollow Technologies. Mr. Patel previously held research and development positions at EndoTex Interventional Systems and General Surgical Innovations. Mr. Patel holds a B.S. in Mechanical Engineering from M.S. University of Baroda, India, and an M.S. in Mechanical Engineering from the University of Florida.

**Code of Business Conduct**

We have adopted a code of business conduct that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct is available on our website at *www.avinger.com*. Updates to or waivers of the code will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the code in the future by disclosing such information on our website.

**Board Leadership Structure**

We believe that the structure of our board of directors and its committees provides strong overall management of our company. Our board of directors does not have a formal policy on whether the roles of Chief Executive Officer and Chairman of our board of directors should be separate. However, Messrs. Soinski and Cullen, respectively, hold these positions at present.

Our Chief Executive Officer, Mr. Soinski, is responsible for setting the strategic direction of our company, the general management and operation of the business and the guidance and oversight of senior management. In his capacity as Chairman of our board of directors, Mr. Cullen is also responsible for the guidance and oversight of senior management, monitoring the content, quality and timeliness of information sent to our board of directors, consultation with our board of directors regarding the oversight of our business affairs, presiding over meetings of our board of directors and performing such additional duties as our Board may otherwise determine and delegate. At the end of each board meeting, the independent directors are expected to meet in executive session, without Mr. Soinski present. Following each meeting, Mr. Cullen is expected to provide feedback to Mr. Soinski on his performance and the performance of our employees during the meeting and to recommend new agenda items for the next meeting.

**Director Independence**

Our common stock is listed on The Nasdaq Capital Market. Under the Nasdaq listing standards, independent directors must comprise a majority of a listed company's board of directors. In addition, the Nasdaq listing standards require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent. Under the Nasdaq listing standards, a director will only qualify as an "independent director" if, in the opinion of that listed company's board of directors, that director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the additional independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the "Exchange Act, and the Nasdaq listing standards. Compensation committee members must also satisfy the additional independence criteria set forth in Rule 10C-1 under the Exchange Act and the Nasdaq listing standards.

Our board of directors has undertaken a review of the independence of each of our directors. Based on information provided by each director concerning his background, employment and affiliations, our board of directors has determined that Messrs. Cullen, McElwee and Dr. Elias do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq listing standards. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described below under the heading "*Related Person Transactions.*"

**Board Meetings and Committees**

During our fiscal year ended December 31, 2021, our board of directors held 12 meetings (including regularly scheduled and special meetings), and each director attended at least 75% of the aggregate of (i) the total number of meetings of our board of directors held during the period for which he has been a director and (ii) the total number of meetings held by all committees of our board of directors on which he served during the periods that he served. All of our directors who were directors at the time attended our 2021 annual meeting of stockholders telephonically.

Although we do not have a formal policy regarding attendance by members of our board of directors at annual meetings of stockholders, we strongly encourage our directors to attend.

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members will serve on these committees until their resignation or until as otherwise determined by our board of directors.

***Audit Committee***

Messrs. McElwee, Cullen and Dr. Elias serve on our audit committee. Mr. Cullen serves as the chair of the audit committee. Our board of directors has assessed whether all members of the audit committee meet the composition requirements of Nasdaq, including the requirements regarding financial literacy and financial sophistication. Our board of directors found that Messrs. McElwee, Cullen and Dr. Elias have met the financial literacy and financial sophistication requirements and that Messrs. McElwee, Cullen and Dr. Elias are independent under SEC and Nasdaq rules. In addition, our board of directors has determined that Mr. Cullen is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act of 1933, as amended, or the Securities Act. The audit committee's primary responsibilities include:

- appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is Moss Adams LLP;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statements;
- monitoring our internal control over financial reporting, disclosure controls and procedures;
- reviewing our risk management status;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management; and
- monitoring compliance with the code of business conduct and ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our audit committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq listing standards. A copy of the charter of our audit committee is available on our website at *www.avinger.com* under "*Investors–Governance*." During our fiscal year ended December 31, 2021, our audit committee held four meetings.

***Compensation Committee***

Messrs. Cullen, McElwee and Dr. Elias serve on our compensation committee. Mr. McElwee serves as the chair of the compensation committee. Each member of our compensation committee meets the requirements for independence for compensation committee members under the Nasdaq listing standards and SEC rules and regulations, including Rule 10C-1 under the Exchange Act. Each member of our compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code. Our compensation committee is responsible for, among other things:

- annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- determining the compensation of our chief executive officer and our other executive officers;
- reviewing and making recommendations to our board of directors with respect to director compensation; and
- overseeing and administering our equity incentive plans.

Our Chief Executive Officer and Chief Financial Officer make compensation recommendations for our other executive officers and initially propose the corporate and departmental performance objectives under our Executive Incentive Compensation Plan to the compensation committee. From time to time, the compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, we have periodically engaged Radford, a business unit of Aon Hewitt, to help develop our compensation philosophy, select a group of peer companies to use for compensation benchmarking purposes and advise on cash and equity compensation levels for our directors, executives and other employees based on current market practices. We did not use any compensation consultants during our year ended December 31, 2021. Our compensation committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq listing standards. A copy of the charter of our compensation committee is available on our website at *www.avinger.com* under "*Investors–Governance*." During our fiscal year ended December 31, 2021, our compensation committee held three meetings.

***Nominating and Corporate Governance Committee***

Messrs. Cullen, McElwee and Dr. Elias serve on our nominating and governance committee. Dr. Elias serves as the chair of the nominating and governance committee. Each member of our nominating and corporate governance committee meets the requirements for independence under the Nasdaq listing standards and SEC rules and regulations. Our nominating and corporate governance committee is responsible for, among other things:

- identifying individuals qualified to become members of our board of directors;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board of directors with respect to management succession planning;
- developing, updating and recommending to our board of directors corporate governance principles and policies; and
- overseeing the evaluation of our board of directors and committees.

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable Nasdaq listing standards. A copy of the charter of our nominating and corporate governance committee is available on our website at *www.avinger.com* under "*Investors–Governance*." During our fiscal year ended December 31, 2021, our nominating and corporate governance committee held no meetings.

*Considerations in Evaluating Director Nominees*

Our nominating and corporate governance committee uses a variety of methods for identifying and evaluating director nominees. In its evaluation of director candidates, our nominating and corporate governance committee will consider the current size and composition of our board of directors and the needs of our board of directors and the respective committees of our board of directors. Some of the qualifications that our nominating and corporate governance committee considers include, without limitation, issues of character, integrity, judgment, diversity of experience, independence, area of expertise, corporate experience, length of service, potential conflicts of interest and other commitments. We also look for nominees who have skills and experience that would support the short and long-term goals and strategy of the Company. Our nominating and corporate governance committee seeks to maintain an appropriate balance of backgrounds, skills, knowledge, and experience to support current and future needs. Nominees must also have the ability to offer advice and guidance to our Chief Executive Officer based on past experience in positions with a high degree of responsibility and be leaders in the companies or institutions with which they are affiliated.

In the case of incumbent directors whose terms of office are set to expire, our nominating and corporate governance committee reviews these directors' overall service to the Company during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence.

Director candidates, including incumbent directors, must have sufficient time available in the judgment of our nominating and corporate governance committee to perform all board of director and committee responsibilities. Members of our board of directors are expected to prepare for, attend and participate in all board of director and applicable committee meetings. Other than the foregoing, there are no stated minimum criteria for director nominees, although our nominating and corporate governance committee may also consider such other factors as it may deem, from time to time, are in our and our stockholders' best interests.

Although our board of directors does not maintain a specific policy with respect to board diversity, our board of directors believes that our board of directors should be a diverse body, and our nominating and corporate governance committee considers a broad range of backgrounds and experiences. In making determinations regarding nominations of directors, our nominating and corporate governance committee may take into account the benefits of diverse viewpoints, backgrounds, and experiences. Our nominating and corporate governance committee also considers these and other factors as it oversees the annual board of director and committee evaluations. After completing its review and evaluation of director candidates, our nominating and corporate governance committee recommends to our full board of directors the director nominees for selection.

In addition to utilizing personal networks and relationships to identify potential candidates, our nominating and corporate governance committee may also engage, if it deems appropriate, a professional search firm. The nominating and corporate governance committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the board. The nominating and corporate governance committee meets to discuss and consider the candidates' qualifications and then selects a nominee for recommendation to the board.

*Stockholder Recommendations for Nominations to the Board of Directors*

Our nominating and corporate governance committee will consider candidates for director recommended by stockholders, so long as such recommendations comply with our amended and restated certificate of incorporation, amended and restated bylaws and applicable laws, rules and regulations, including those promulgated by the SEC. Our nominating and corporate governance committee will evaluate such recommendations in accordance with its charter, our amended and restated bylaws, our policies and procedures for director candidates, as well as the regular director nominee criteria described above. This process is designed to ensure that our board of directors includes members with diverse backgrounds, skills and experience, including appropriate financial and other expertise relevant to our business. Eligible stockholders wishing to recommend a candidate for nomination should contact our Secretary in writing. Such recommendations must include information about the candidate, a statement of support by the recommending stockholder, evidence of the recommending stockholder's ownership of our common stock and a signed letter from the candidate confirming willingness to serve on our board of directors. Our nominating and corporate governance committee has discretion to decide which individuals to recommend for nomination as directors.

Under our amended and restated bylaws, stockholders may also nominate candidates for our board of directors. Any nomination must comply with the requirements set forth in our amended and restated bylaws and should be sent in writing to our Secretary at 400 Chesapeake Drive, Redwood City, California 94063. To be timely for our 2022 annual meeting of stockholders, our Secretary must receive the nomination no earlier than August 22, 2022 and no later than September 21, 2022.

## ITEM 11. EXECUTIVE COMPENSATION

### Processes and Procedures for Compensation Decisions

Our compensation committee is responsible for the executive compensation programs for our executive officers and reports to our board of directors on its discussions, decisions and other actions. Our compensation committee reviews and approves corporate goals and objectives relating to the compensation of our Chief Executive Officer, evaluates the performance of our Chief Executive Officer in light of those goals and objectives and determines and approves the compensation of our Chief Executive Officer based on such evaluation. Our compensation committee has the sole authority to determine our Chief Executive Officer's compensation. In addition, our compensation committee, in consultation with our Chief Executive Officer, reviews and approves all compensation for other officers. Our Chief Executive Officer and Chief Financial Officer also make compensation recommendations for our other executive officers and initially propose the corporate and departmental performance objectives under our Executive Incentive Compensation Plan to the compensation committee.

The compensation committee is authorized to retain the services of one or more executive compensation and benefits consultants or other outside experts or advisors as it sees fit, in connection with the establishment of our compensation programs and related policies.

**Summary Compensation Table**

The following table presents summary information regarding the total compensation for services rendered in all capacities that was earned by our Chief Executive Officer and our two other most highly compensated executive officers in our fiscal years ended December 31, 2021 and 2020. The individuals listed in the table below are our named executive officers for our fiscal year ended December 31, 2021.

| Name and Principal Position | Year | Salary ($)(1) | Bonus ($) | Stock Awards ($) | Option Awards ($) | Non-Equity Incentive Plan Compensation ($)(2) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|
| Jeffrey M. Soinski | 2021 | 400,000 | - | - | - | 194,824 | - | 594,824 |
| *President and Chief Executive Officer* | 2020 | 376,667 | - | - | - | 128,236 | - | 504,903 |
| Himanshu Patel | 2021 | 300,000 | - | - | - | 116,047 | - | 416,047 |
| *Chief Technology Officer* | 2020 | 282,500 | - | - | - | 76,942 | - | 359,442 |
| Mark B. Weinswig | 2021 | 300,000 | - | - | - | 115,411 | - | 415,411 |
| *Chief Financial Officer* | 2020 | 282,500 | - | - | - | 76,942 | - | 359,442 |

(1) The amounts reported for 2020 are inclusive of salary reductions for the above individuals as part of temporary cost saving measures employed by the company due to the adverse effects of COVID-19 pandemic on its business.

(2) Non-equity incentive plan compensation includes cash awards granted at the discretion of the Compensation Committee under our Executive Incentive Compensation Plan for achieving certain performance-based criteria.

**Executive Employment Letters**

***Jeffrey M. Soinski***

Pursuant to the employment letter, as revised on September 9, 2020, between the Company and Jeffrey M. Soinski, our President and Chief Executive Officer, Mr. Soinski is entitled to receive as compensation (i) a base salary of $400,000, (ii) a discretionary bonus targeted at 75% of his base salary, subject to the achievement of certain goals mutually agreed upon by him and our board of directors and payable semi-annually; and (iii) other standard benefits provided to each of the Company's executive officers. The letter has no specific term and provides for at-will employment.

Pursuant to Mr. Soinski's employment offer letter, if, within the 12-month period following a "change in control," we terminate Mr. Soinski's employment without "cause," or Mr. Soinski resigns for "good reason" (as such terms are defined in Mr. Soinski's employment offer letter), Mr. Soinski will receive accelerated vesting as to 100% of his outstanding unvested stock options. If we experience a change in control, and Mr. Soinski remains our employee through such date, Mr. Soinski will receive accelerated vesting as to 50% of his outstanding unvested stock options and/or restricted stock.

If we terminate Mr. Soinski without cause at any time, he will be entitled to receive 12 months of base salary and COBRA medical and dental insurance coverage, in each case payable in substantially equal installments in accordance with our payroll practices, as severance, in exchange for signing and not revoking a severance agreement and general release against us and our affiliates within 60 days following his termination of employment.

***Mark Weinswig***

Pursuant to an employment offer letter between the Company and Mr. Weinswig, dated as of June 11, 2018, Mr. Weinswig is entitled to receive as compensation (i) a base salary of $300,000; (ii) a discretionary bonus targeted at 40% of his base salary, subject to achievement of mutually agreed performance goals and payable semi-annually; and (iii) other standard benefits provided to each of the Company's executive officers. On September 9, 2020, Mr. Weinswig's target bonus percentage was increased from 40% to 60%.

**401(k) Plan**

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. We may make a discretionary matching contribution to the 401(k) plan, and may make a discretionary employer contribution to each eligible employee each year. To date, we have not made any matching or profits sharing contributions into the 401(k) plan. All participants' interests in our matching and profit sharing contributions, if any, vest pursuant to a four-year graded vesting schedule from the time of contribution. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all contributions are deductible by us when made.

**Pension Benefits and Nonqualified Deferred Compensation**

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2021.

**Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding equity awards held by our named executive officers at December 31, 2021.

| | | Option Awards | | | | Stock Awards | |
|---|---|---|---|---|---|---|---|
| Name | Grant Date | Number of Securities Underlying Unexercised Options (#) Exercisable (3) | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($)(4) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested ($)(5) |
| Jeffrey M. Soinski | 12/31/2014(1)(7) | 77 | — | 36,000 | 12/31/2024 | — | — |
| | 3/7/2016 (2)(7) | 8 | — | 103,680 | 3/7/2026 | — | — |
| | 3/13/2017 (2) (7) | 8 | — | 16,400 | 3/13/2027 | — | — |
| | 9/18/2019(2) (8) | — | — | — | — | 1,250 | 11,250 |
| | | | | | | | |
| Himanshu Patel | 11/5/2013 (1) (6) | 3 | — | 162,000 | 11/5/2023 | — | — |
| | 12/31/2014(1)(7) | 22 | — | 36,000 | 12/31/2024 | — | — |
| | 3/3/2016(2) (7) | 3 | — | 103,920 | 3/3/2026 | — | — |
| | 3/13/2017 (2) (7) | 4 | — | 16,400 | 3/13/2027 | — | — |
| | 9/18/2019(2) (8) | — | — | — | — | 833 | 7,497 |
| | | | | | | | |
| Mark Weinswig | 9/18/2019(2) (8) | — | — | — | — | 833 | 7,497 |

(1) Each of the outstanding equity awards was granted pursuant to our 2009 Stock Plan. No additional awards may be granted under the 2009 Stock Plan, and all awards granted under the 2009 Stock Plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued become available for grant under the 2015 Plan in accordance with its terms.

(2) Each of the outstanding equity awards was granted pursuant to our 2015 Equity Incentive Plan.

(3) All of our options granted pursuant to our 2009 Stock Plan are early exercisable subject to the Company's right to repurchase any unvested shares.

(4) This column represents the fair value of a share of our common stock on the date of grant, as determined by our board of directors.

(5) This column represents the market value of the unvested shares of our common stock underlying the RSUs as of December 31, 2021, based on the closing price of our common stock, as reported on the Nasdaq Global Select Market, of $9.00 per share.

(6) 25% of the shares of our common stock subject to this option vested on October 11, 2014, and the balance vested in 36 successive equal monthly installments, subject to continued service through each such vesting date.

(7) 25% of the shares of our common stock subject to this option vested on the one year anniversary of the grant date, and the balance vests in 36 successive equal monthly installments, subject to continued service through each such vesting date.

(8) 33.3% of the shares of our common stock subject to this stock award vests on the one year anniversary of the grant date, and the balance vests in 2 successive equal annual installments, subject to continued service through each such vesting date.

**Potential Payments upon Termination or Change of Control**

***Jeffrey M. Soinski***

In March 2018, we entered into a change of control and severance agreement with Jeffrey M. Soinski, which was subsequently amended in March 2020. Under this agreement, as amended, if, within the 18 month period following a "change of control," we terminate Mr. Soinski's employment other than for "cause," death or disability, or the employee resigns for "good reason" (as such terms are defined in the employee's employment agreement) and, within 60 days following the employee's termination, the employee executes an irrevocable separation agreement and release of claims, the employee is entitled to receive (i) continuing payments of severance pay at a rate equal to the employee's monthly base salary and pro-rated target bonus, as then in effect, for a period of 12 months plus one month for every year of service completed for the Company (provided that such severance shall not exceed 18 months), (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for employee and employee's dependents for up to 12 months, (iii) accelerated vesting as to 100% of the employee's outstanding unvested stock options and/or restricted stock, and (iv) the extension of the post-termination exercise period of any options held by the employee for a period of 1 year. Additionally, if we experience a change in control, 50% of Mr. Soinski's outstanding unvested stock options and/or restricted stock will vest. In the event of any conflict between Mr. Soinski's change of control and severance agreement and his offer letter, described above under "*Executive Employment Letters*," he will be entitled to the greater of the benefits provided by either. The agreement also provides that if the employee is employed by the Company or the Company's successor on the date that is 12 months following a change of control, then the employee will be entitled to a lump sum bonus payment in an amount equal to what the employee would have received as a severance payment if the employee had been terminated other than for cause, death or disability.

***Himanshu Patel***

We previously entered into a change of control and severance agreement with Himanshu Patel, which was subsequently amended in March 2020. Under this agreement, as amended, if, within the 18 month period following a "change of control," we terminate Mr. Patel's employment other than for "cause," death or disability, or the employee resigns for "good reason" (as such terms are defined in the employee's employment agreement) and, within 60 days following the employee's termination, the employee executes an irrevocable separation agreement and release of claims, the employee is entitled to receive (i) continuing payments of severance pay at a rate equal to the employee's monthly base salary and pro-rated target bonus, as then in effect, for a period of 12 months plus one month for every year of service completed for the Company (provided that such severance shall not exceed 18 months), (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for employee and employee's dependents for up to 12 months, (iii) accelerated vesting as to 100% of the employee's outstanding unvested stock options and/or restricted stock, and (iv) the extension of the post-termination exercise period of any options held by the employee for a period of 1 year. The agreement also provides that if the employee is employed by the Company or the Company's successor on the date that is 12 months following a change of control, then the employee will be entitled to a lump sum bonus payment in an amount equal to what the employee would have received as a severance payment if the employee had been terminated other than for cause, death or disability.

***Mark Weinswig***

In June 2018, we entered into a change of control and severance agreement with Mark Weinswig, which was subsequently amended in March 2020. Under this agreement, as amended, if, within the 18 month period following a "change of control," we terminate Mr. Weinswig's employment other than for "cause," death or disability, or the employee resigns for "good reason" (as such terms are defined in the employee's employment agreement) and, within 60 days following the employee's termination, the employee executes an irrevocable separation agreement and release of claims, the employee is entitled to receive (i) continuing payments of severance pay at a rate equal to the employee's monthly base salary and pro rated target bonus, as then in effect, for 12 months plus one month for every year of service completed for the Company (provided that such severance shall not exceed 18 months), (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for employee and employee's dependents for up to 12 months, (iii) accelerated vesting as to 100% of the employee's outstanding unvested stock options and/or restricted stock, and (iv) the extension of the post-termination exercise period of any options held by the employee for a period of 1 year. Additionally, if we experience a change in control, 50% of Mr. Weinswig's outstanding unvested stock options and/or restricted stock will vest. In the event of any conflict between Mr. Weinswig's change of control and severance agreement and his offer letter, described above under "*Executive Employment Letters*," he will be entitled to the greater of the benefits provided by either. The agreement also provides that if the employee is employed by the Company or the Company's successor on the date that is 12 months following a change of control, then the employee will be entitled to a lump sum bonus payment in an amount equal to what the employee would have received as a severance payment if the employee had been terminated other than for cause, death or disability.

**Executive Incentive Compensation Plan**

Our board of directors has adopted an Executive Incentive Compensation Plan, or the Bonus Plan, that is administered by our compensation committee. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, based upon performance goals established by our compensation committee.

Under the Bonus Plan, our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation: attainment of research and development milestones, sales bookings, business divestitures and acquisitions, cash flow, cash position, earnings (which may include any calculation of earnings, including but not limited to earnings before interest and taxes, earnings before taxes, earnings before interest, taxes, depreciation and amortization and net earnings), earnings per share, net income, net profit, net sales, operating cash flow, operating expenses, operating income, operating margin, overhead or other expense reduction, product defect measures, product release timelines, productivity, profit, return on assets, return on capital, return on equity, return on investment, return on sales, revenue, revenue growth, sales results, sales growth, stock price, time to market, total stockholder return, working capital, and individual objectives such as peer reviews or other subjective or objective criteria. Performance goals that include our financial results may be determined in accordance with GAAP or such financial results may consist of non-GAAP financial measures and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when performance goals that include our financial results may be determined in accordance with GAAP, or such financial results may consist of non-GAAP financial measures, and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when determining whether the performance goals have been met. The goals may be on the basis of any factors the compensation committee determines relevant, and may be adjusted on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the compensation committee's discretion. Our compensation committee may determine the amount of any reduction on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards are paid in cash only after they are earned, which usually requires continued employment through the date a bonus is paid. Our compensation committee has the authority to amend, alter, suspend or terminate the Bonus Plan provided such action does not impair the existing rights of any participant with respect to any earned bonus.

*Retention Bonuses*

On March 9, 2021, the Compensation Committee (the "Committee") of the Board of Directors of the Company determined to provide certain incentive payments (the "Retention Bonuses") to certain full-time executive officers and vice presidents of the Company, including Jeffrey M. Soinski, Mark Weinswig, and Himanshu Patel, who serve as the Company's Chief Executive Officer, Chief Financial Officer, and Chief Technology Officer, respectively (the "Bonus Officers"), based on certain performance goals. The Retention Bonus consists of incentive payments in an amount equal to 100% of such Bonus Officer's annual salary as of December 31, 2023, 50% of which will be paid if such Bonus Officer is in good standing in their service at the Company on December 31, 2023, and 50% to be paid if such Bonus Officer is in good standing in their service at the Company on December 31, 2024 (each, a "Retention Bonus Payment"). The Retention Bonus Payments may be paid in cash or equity, or a combination of both, as determined by the Committee. In addition, the Retention Bonus Payments shall accelerate in the event of a Change in Control, as defined in the Company's Amended and Restated 2015 Equity Incentive Plan, provided that the Bonus Officer remains in his or her respective position through such Change in Control. Each Retention Bonus Payment shall be increased in the event that the price of the common stock of the Company is above $60.00 (subject to adjustment for any stock splits, reverse stock splits, or similar transactions) as of the date of such Retention Bonus Payment, according to the schedule below:

- If the stock price is between $60.00 and $79.99 (subject to adjustment for any stock splits, reverse stock splits, or similar transactions) as of the date of the Retention Bonus Payment, such Retention Bonus Payment shall be increased by 25%;

- If the stock price is between $80.00 and $99.99 (subject to adjustment for any stock splits, reverse stock splits, or similar transactions) as of the date of the Retention Bonus Payment, such Retention Bonus Payment shall be increased by 50%; and

- If the stock price is $100.00 or above (subject to adjustment for any stock splits, reverse stock splits, or similar transactions) as of the date of the Retention Bonus Payment, such Retention Bonus Payment shall be increased by 100%.

The Retention Bonuses are in addition to any other bonus to which the Bonus Officers may be entitled under the Company's Bonus Plan.

**Director Compensation**

Our board of directors approved our Outside Director Compensation Policy in January 2015 to compensate each non-employee director for his or her service, and amended certain aspects of this policy in August 2018. Our board of directors will have the discretion to revise non-employee director compensation as it deems necessary or appropriate. Under our Outside Director Compensation Policy, non-employee directors will receive compensation in the form of equity and cash, as described below:

*Cash Compensation.* All non-employee directors will be entitled to receive the following cash compensation for their services:

- $35,000 per year for service as a board member;
- $25,000 per year additionally for service as chairman of the board;
- $20,000 per year additionally for service as chairman of the audit committee;
- $10,000 per year additionally for service as an audit committee member;
- $15,000 per year additionally for service as chairman of the compensation committee;
- $7,500 per year additionally for service as a compensation committee member;
- $10,000 per year additionally for service as chairman of the nominating and corporate governance committee; and
- $5,000 per year additionally for service as a nominating and corporate governance committee member.

All cash payments to non-employee directors, or the Retainer Cash Payments, will be paid semiannually with the first semiannual installment payable on the date of our annual meeting of stockholders or, if no annual meeting occurs in a given year, May 1, and the second semiannual installment payable on November 1 of each year.

*Election to Receive RSUs in Lieu of Cash Payments.* All non-employee directors may elect to convert a Retainer Cash Payment into RSUs, or Retainer RSUs, with a grant date fair value equal to the applicable Retainer Cash Payment. Each Retainer RSU will be granted on the date that the applicable Retainer Cash Payment was scheduled to be paid, and all of the shares underlying the Retainer RSUs will vest and become exercisable six months from the date of grant, subject to continued service as a director through the applicable vesting date. The Retainer RSUs will be subject to certain terms and conditions as described below under the section titled "*Director Compensation—Equity Compensation*."

Elections to convert a Retainer Cash Payment into a Retainer RSU must generally be made on or prior to December 31 of the year prior to the year in which the Retainer Cash Payment is scheduled to be paid, or such earlier deadline as is established by our board of directors or compensation committee. A newly appointed non-employee director will be permitted to elect to convert Retainer Cash Payments payable in the same calendar year into Retainer RSUs, provided that such election is made prior to the date the individual becomes a non-employee director.

*Equity Compensation.* Nondiscretionary, automatic grants of RSUs will be made to our non-employee directors.

- *Initial Grant*. Generally, each person who first becomes a non-employee director will be granted RSUs having a grant date fair value equal to $115,000, or the Initial Grant. The Initial Grant will typically be granted on the date of the first meeting of our board of directors or compensation committee occurring on or after the date on which the individual first became a non-employee director. The Initial Grant will vest and become exercisable as to one thirty-sixth (1/36th) of the shares subject to such Initial Grant on each monthly anniversary of the commencement of the non-employee director's service as a director, subject to the continued service as a director through the applicable vesting date.

- *Annual Grant*. Once each calendar year, on the same date that our board of directors grants annual equity awards to our senior executives, each non-employee director will be granted RSUs having a grant date fair value equal to $75,000, or the Annual Grant. All of the shares underlying the Annual Grant will vest and become exercisable one year from the date of grant, subject to continued service as a director through the applicable vesting date.

The grant date fair value is the closing sales price for the Company's common stock (or the closing bid, if no sales were reported) as quoted on such exchange or system on the date such award is granted.

Any RSUs granted under our outside director compensation policy will fully vest and become exercisable in the event of a change in control, as defined in our 2015 Plan, provided that the holder remains a director through such change in control. Further, our 2015 Plan provides that in the event of a merger or change in control, as defined in our 2015 Plan, each outstanding equity award granted under our 2015 Plan that is held by a non-employee director will fully vest, all restrictions on the shares subject to such award will lapse and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels, and all of the shares subject to such award will become fully exercisable, if applicable, provided such optionee remains a director through such merger or change in control.

*2021 Changes to Director Compensation*

Notwithstanding the above, pursuant to the authority of our board of directors to revise non-employee director compensation, our board of directors has deemed it appropriate and necessary to pay the Annual Grant for the year 2021 in the amount of $75,000 in cash, in lieu of making the 2021 Annual Grant in the form of RSUs.

*Compensation for Fiscal Year 2021*

The following table sets forth a summary of the compensation received by our non-employee directors who received compensation during our fiscal year ended December 31, 2021:

| Name | Fees earned or paid in cash | Option awards(1) | Stock awards(2) | Total |
|---|---|---|---|---|
| James G. Cullen | $ 92,500 | $ - | $ - | $ 92,500 |
| James B. McElwee | 65,000 | - | - | 65,000 |
| Tamara Elias (3) | 62,500 | - | 145,000 | 207,500 |

(1) As of December 31, 2021, Messrs. Cullen and McElwee had outstanding options to purchase a total of 3,429 and 274 shares of our common stock, respectively.
(2) During 2021, all non-employee directors that were directors at the time of grant did not receive an Annual RSU grant due to insufficient shares available within the 2015 Stock Plan.
(3) During 2021, Dr. Elias received an RSU grant totaling $145,000 as compensation for her appointment to the board of directors on December 12, 2019. As of December 31, 2021, Dr. Elias had a total of 2,250 outstanding RSUs.

Directors who are also our employees receive no additional compensation for their service as directors. During 2021, Jeffrey M. Soinski, our President, Chief Executive Officer and a director, was also our employee. See the section titled "*Summary Compensation Table*" below for additional information about the compensation for Mr. Soinski.

**Officer and Director Share Purchase Plan**

On August 22, 2018, the Board of Directors of the Company approved the adoption of an Officer and Director Share Purchase Plan ("ODPP"), which allows executive officers and directors to purchase shares of our common stock at fair market value in lieu of salary or, in the case of directors, director fees. Eligible individuals may voluntarily participate in the ODPP by authorizing payroll deductions or, in the case of directors, deductions from director fees for the purpose of purchasing common stock. Elections to participate in the ODPP may only be made during open trading windows under our insider trading policy when the participant does not otherwise possess material non-public information concerning the Company. The Board of Directors authorized 1,000 shares to be made available for purchase by officers and directors under the ODPP. Effective on August 28, 2019 and March 10, 2020, the Board of Directors approved an additional 2,000 and 6,250 shares, respectively, to be made available under the ODPP. Common stock issued under the ODPP during the year ended December 31, 2020 totaled 2,652 shares. As of December 31, 2021, there were 4,609 shares reserved for issuance under the ODPP.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

**Equity Compensation Plan Information**

All of our equity compensation plans have been approved by our stockholders. The following table provides information as of December 31, 2021, with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

| Plan Category | (a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Restricted Stock Units and Rights | (b) Weighted Average Exercise Price of Outstanding Options, Restricted Stock Units and Rights (2) | (c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) |
|---|---|---|---|
| Equity compensation plans approved by stockholders (1) | 10,381 | $ 23,816.00 | 8,480 |

(1) Includes the following plans: our 2009 Stock Plan and our 2015 Plan. Our 2015 Plan provides that on the first day of each fiscal year commencing in fiscal year 2016, the number of shares authorized for issuance under the 2015 Plan is automatically increased by a number equal to the lesser of (i) 211 shares of common stock, (ii) 5.0% of the aggregate number of shares of common stock outstanding on the last day of the preceding fiscal year, or (iii) such number of shares that may be determined by our board of directors.

(2) The weighted average exercise price does not take into account outstanding restricted stock, or RSUs, which have no exercise price.

**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information with respect to the beneficial ownership of our capital stock as of December 31, 2021 for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers;
- each of our directors and nominees for director; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of our capital stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 4,778,263 shares of our common stock outstanding as of December 31, 2021. In computing the number of shares of capital stock beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares of our capital stock subject to options held by the person that are currently exercisable or exercisable within 60 days of December 31, 2021. However, we did not deem such shares of our capital stock outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Avinger, Inc., 400 Chesapeake Drive, Redwood City, California 94063. The information provided in the table is based on our records, information filed with the SEC and information provided to us, except where otherwise noted.

| Name of Beneficial Owner | Shares Beneficially Owned | |
|---|---|---|
| | Number of Shares | Percentage |
| **Named Executive Officers and Directors:** | | |
| Jeffrey M. Soinski(1) | 5,913 | * |
| Himanshu Patel(2) | 14,536 | * |
| Mark Weinswig(3) | 4,019 | * |
| James G. Cullen(4) | 3,662 | * |
| James B. McElwee(5) | 3,507 | * |
| Tamara N. Elias (6) | 2,250 | * |
| All executive officers, directors and director nominees as a group (6 individuals)(7) | 33,887 | * |

* Represents ownership of less than 1%

(1) Consists of (i) 5,820 shares of common stock held of record by Mr. Soinski, and (ii) 93 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2021.

(2) Consists of (i) 4,254 shares of common stock held of record by Mr. Patel, (ii) warrants to purchase 250 shares of common stock, (iii) 32 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2021, and (iv) 10,000 shares of common stock that are issuable upon the conversion of shares of Series B preferred stock that are immediately convertible to common stock.

(3) Consists of 4,019 shares of common stock held of record by Mr. Weinswig.

(4) Consists of (i) 3,491 shares of common stock held of record by 2000 James Cullen Generation Skipping Family Trust, and (ii) 171 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2021. Mr. Cullen has sole voting and dispositive power with respect to shares held by James Cullen Generation Skipping Family Trust. Mr. Cullen does not have a pecuniary interest in the James Cullen Generation Skipping Family Trust.

(5) Consists of (i) 3,493 shares of common stock held of record by Mr. McElwee, and (ii) 14 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2021.

(6) Consists of 2,250 shares of common stock held of record by Mrs. Elias.

(7) Consists of (i) 23,327 shares of common stock, (ii) warrants to purchase 250 shares of common stock, (iii) 310 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2021 and (iv) 10,000 shares of common stock that are issuable upon the conversion of shares of Series B preferred stock that are immediately convertible to common stock.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

### Related Person Transactions

We describe below transactions and series of similar transactions, since January 1, 2020, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years; and
- any of our directors, nominees for director, executive officers or beneficial holders of more than 5% of our outstanding common stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities (each, a related person), had or will have a direct or indirect material interest.

We have entered into employment and separation arrangements with certain current and former executive officers. For more information on these employment and separation agreements, see the section titled “Executive Compensation - Executive Employment Letters” in Item 11 above.

We have entered into indemnification agreements with our directors and executive officers. The indemnification agreements, as well as our certificate of incorporation and bylaws, require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law.

*Policies and Procedures for Related Party Transactions*

Our board of directors has adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock or any member of the immediate family of any of the foregoing persons in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years and such person would have a direct or indirect interest must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

### Director Independence

Information regarding the independence of directors is disclosed above under Item 10 under the heading “Director Independence” and incorporated herein by reference.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

### Fees Paid to the Independent Registered Public Accounting Firm

The following table represents aggregate fees billed to us for the years ended December 31, 2021 and 2020 by Moss Adams, as applicable. All fees below were approved by our Audit Committee.

| Year ending December 31, | 2021 | 2020 |
|---|---|---|
| Audit fees(1)(2) | $ 414,750 | $ 629,041 |
| Audit related fees | — | 14,450 |
| All other fees(3) | 1,725 | — |
| Total | $ 416,475 | $ 643,491 |

(1) Audit fees consist of fees incurred for professional services rendered for the audit of our annual financial statements and review of the quarterly financial statements, assistance with registration statements filed with the SEC, and services that are normally provided by our independent registered public accounting firm in connection with regulatory filings or engagements.
(2) For the years ended December 31, 2021 and 2020, audit fees also include fees related to our public offerings and review of documents filed with the SEC of $52,500 and $281,491, respectively.
(3) For the years ended December 31, 2021 all other fees was comprised of consultations relating to sales tax matters.

### Auditor Independence

In our fiscal year ended December 31, 2021, there were no other professional services provided by Moss Adams that would have required our audit committee to consider their compatibility with maintaining the independence of Moss Adams.

### Audit Committee Policy on Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee has established a policy governing our use of the services of our independent registered public accounting firm. Under this policy, our audit committee is required to pre-approve all audit and non-audit services performed by our independent registered public accounting firm in order to ensure that the provision of such services does not impair the public accountants' independence. All fees paid to Moss Adams for our fiscal years ended December 31, 2021 and 2020 were pre-approved by our audit committee.

## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

### (a)(1) Financial Statements

The following Financial Statements are filed as part of this Annual Report on Form 10-K:



### (a)(2) Financial Statement Schedules

All other schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto. Financial statement schedules relating to the allowance for doubtful accounts receivable and for sales returns follows (in thousands):

| Description | Balance at Beginning of Year | Charged to costs and expenses | Write offs | Balance at End of Year |
|---|---|---|---|---|
| **Allowance for doubtful accounts receivable:** | | | | |
| Fiscal year ended 2020 | $ 19 | $ 26 | $ 26 | $ 19 |
| Fiscal year ended 2021 | $ 19 | $ 2 | $ 15 | $ 6 |

| | Balance at Beginning of Year | Charged to costs and expenses | Write offs | Balance at End of Year |
|---|---|---|---|---|
| **Allowance for sales returns:** | | | | |
| Fiscal year ended 2020 | $ 6 | $ 29 | $ 15 | $ 20 |
| Fiscal year ended 2021 | $ 20 | $ 10 | $ 10 | $ 20 |

**(a)(3) Exhibits**

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

| Exhibit Number | Exhibit Title |
|---|---|
| 3.1 (1) | Amended and Restated Certificate of Incorporation of the registrant. |
| 3.2 (1) | Bylaws of the registrant. |
| 3.3 (2) | Certificate of Amendment to the Amended and Restated Certificate of Incorporation. |
| 3.4 (3) | Avinger, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock |
| 3.5 (4) | Avinger, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock |
| 3.6 (5) | Avinger, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock |
| 3.7 (5) | Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock |
| 3.8 (6) | Certificate of Amendment to the Restated Certificate of Incorporation of Avinger, Inc. |
| 3.9 (7) | Amendment to the Amended and Restated Bylaws of Avinger, Inc., dated as of October 27, 2021. |
| 3.10 (8) | Avinger, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock. |
| 3.11 (32) | Certificate of Amendment to the Restated Certificate of Incorporation Avinger, Inc. dated March 11, 2022. |
| 4.1 (9) | Specimen Common Stock certificate of the registrant. |
| 4.2 (5) | Specimen Series 1/2 warrant of the registrant. |
| 4.3 (10) | Form of Common Stock Purchase Warrant |
| 4.4 (11) | Description of Registrant's Securities |
| 4.5 (12) | Form of Common Stock Purchase Warrant. |
| 4.6 (12) | Form of Placement Agent Warrant. |
| 10.1 (13) | Form of Indemnification Agreement for directors and executive officers. |
| 10.2 (14) | 2009 Stock Plan and Form of Option Agreement thereunder. |
| 10.3 (14) | 2014 Preferred Stock Plan. |
| 10.4 (15) | 2015 Equity Incentive Plan, as amended |
| 10.5 (13) | Form of Restricted Stock Unit Award Agreement. |
| 10.6 (13) | Form of Stock Option Agreement. |
| 10.7 (13) | 2015 Employee Stock Purchase Plan. |
| 10.8 (13) | Executive Incentive Compensation Plan. |
| 10.9 (14) | Amended and Restated Investors' Rights Agreement dated September 2, 2014 by and among the registrant and certain stockholders. |

| Exhibit Number | Exhibit Title |
|---|---|
| 10.10 (14) | Lease Agreement, dated July 30, 2010, by and between the registrant and HCP LS Redwood City, LLC for office space located at 400 and 600 Chesapeake Drive, Redwood City, California. |
| 10.11 (14) | First Amendment to Lease Agreement dated September 30, 2011 by and between registrant and HCP LS Redwood City, LLC. |
| 10.12 (17) | Second Amendment to Lease Agreement dated March 4, 2016 by and between the registrant and HCP LS Redwood City, LLC. |
| 10.13 (14) | Employment Letter dated December 29, 2010 by and between the registrant and Matthew B. Ferguson. |
| 10.14 (14) | Employment Letter dated December 17, 2014 by and between the registrant and Jeffrey M. Soinski. |
| 10.15 (14) | Change of Control and Severance Agreement dated March 1, 2012 by and between the registrant and Matthew B. Ferguson. |
| 10.16 (18) | Change of Control and Severance Agreement dated March 29, 2018 by and between the registrant and Jeffrey M. Soinski. |
| 10.17 (4) | Registration Rights Agreement, dated as of February, 2018, by and among the registrant, CRG Partners III L.P. and certain of its affiliated funds, as purchasers. |
| 10.18 (14) | Note and Warrant Purchase Agreement dated October 29, 2013 by and between the registrant and holders of convertible promissory notes. |
| 10.19 (14) | Amendment No. 1 to the Note and Warrant Purchase Agreement dated May 6, 2014 by and between the registrant and holders of convertible promissory notes. |
| 10.20 (16) | Term Loan Agreement, dated as of September 22, 2015, by and among the registrant, certain of its subsidiaries from time to time party thereto as guarantors and CRG Partners III L.P. and certain of its affiliated funds, as lenders. |
| 10.21 (16) | Securities Purchase Agreement, dated as of September 22, 2015, by and among the registrant, CRG Partners III L.P. and certain of its affiliated funds, as purchasers. |
| 10.23 (17) | Purchase Agreement, dated as of November 3, 2017, by and between the registrant and Lincoln Park Capital Fund, LLC. |
| 10.24 (19) | Registration Rights Agreement, dated as of November 3, 2017, by and between the registrant and Lincoln Park Capital Fund, LLC. |
| 10.26 (20) | Waiver and Consent, dated as of December 14, 2017, by and among the registrant and the lenders party thereto. |
| 10.27 (21) | Waiver and Consent, dated as of January 24, 2018, by and among the registrant and the lenders party thereto. |
| 10.28 (4) | Amendment No. 2 to Term Loan Agreement, dated as of February 14, 2018, by and among the registrant and the lenders party thereto. |
| 10.29 (4) | Series A Preferred Stock Purchase Agreement, dated as of February 14, 2018, by and among the registrant, CRG Partners III L.P. and certain of its affiliated funds, as purchasers. |
| 10.30 (22) | Securities Purchase Agreement, dated as of July 12, 2018, by and among the registrant and the purchasers identified on the signature pages thereto. |
| 10.31 (23) | Separation Agreement and Release, dated as of August 1, 2018, between the registrant and Matt Ferguson. |
| 10.32 (23) | Master Consulting Agreement, dated as of August 1, 2018, between the registrant and Matt Ferguson. |
| 10.33 (23) | Employment Offer Letter, dated as of June 11, 2018, between the registrant and Mark Weinswig. |
| 10.34 (23) | Change of Control and Severance Agreement, dated as of June 25, 2018, between the registrant and Mark Weinswig. |
| 10.35 (24) | Officer and Director Share Purchase Plan. |
| 10.36 (25) | Change of Control and Severance Agreement, dated as of October 10, 2013, between the registrant and Himanshu Patel. |
| 10.37 (26) | Third Amendment to Lease Agreement dated April 1, 2019 by and between the registrant and HCP LS Redwood City, LLC. |
| 10.38 (27) | Amended and Restated 2015 Equity Incentive Plan |
| 10.39 (28) | Amended and Restated Officer and Director Share Purchase Plan |
| 10.40 (11) | Amendment No. 1 to Amended and Restated Officer and Director Share Purchase Plan |
| 10.41 (11) | Amendment No. 3 to Term Loan Agreement dated as of March 2, 2020, by and among the registrant and the lenders party thereto |
| 10.42 (11) | Amendment No. 1 dated March 4, 2020 to the Change of Control and Severance Agreement, dated March 29, 2018, by and between the registrant and Jeff Soinski |
| 10.43 (11) | Amendment No. 1 dated March 4, 2020 to the Change of Control and Severance Agreement, dated October 10, 2013, by and between the registrant and Himanshu Patel |

| | |
|---|---|
| 10.44 (11) | Amendment No. 1 dated March 4, 2020 to the Change of Control and Severance Agreement, dated June 25, 2018, by and between the registrant and Mark Weinswig |
| 10.45 (29) | Promissory Note dated April 20, 2020 between Avinger, Inc. and Silicon Valley Bank |
| 10.46 (30) | Amendment No. 4 and Waiver to Term Loan Agreement |
| 10.47 (31) | Amendment No. 5 to Term Loan Agreement, dated January 22, 2021, made by and among Avinger, Inc. and GRG Partners III L.P. and certain of its affiliated funds, as lenders. |
| 10.48 (12) | Form of Securities Purchase Agreement, dated January 12, 2022 by and between Avinger, Inc. and the purchasers party thereto. |
| 23.1 | Consent of Independent Registered Public Accounting Firm. |
| 24.1 | Power of Attorney (included on signature page). |
| 31.1 | Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |

(1) Previously filed as an Exhibit to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2015, and incorporated by reference herein.
(2) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2018.
(3) Previously filed as an Exhibit to Amendment No. 2 to the registrant's Registration Statement on Form S-1 (File No. 333-222517) filed with the Securities and Exchange Commission on February 12, 2018, and incorporated by reference herein.
(4) Previously filed as an Exhibit to Amendment No. 3 to the registrant's Registration Statement on Form S-1 (File No. 333-222517) filed with the Securities and Exchange Commission on February 13, 2018, and incorporated by reference herein.
(5) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 6, 2018, and incorporated by reference herein.
(6) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 21, 2019, and incorporated by reference herein.
(7) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2021, and incorporated by reference herein.
(8) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 18, 2022, and incorporated by reference herein.
(9) Previously filed as an Exhibit to Amendment No. 2 to the registrant's Registration Statement on Form S-1 (File No. 333-201322) filed with the Securities and Exchange Commission on January 28, 2015, and incorporated by reference herein.
(10) Previously filed as an Exhibit to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-227689) filed with the Securities and Exchange Commission on October 19, 2018, and incorporated by reference herein.
(11) Previously filed as an Exhibit to the registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2020, and incorporated by reference herein.
(12) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 12, 2022, and incorporated by reference herein.
(13) Previously filed as an Exhibit to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-201322) filed with the Securities and Exchange Commission on January 20, 2015, and incorporated by reference herein.

(14) Previously filed as an Exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-201322), filed with the Securities and Exchange Commission on December 30, 2014, and incorporated by reference herein.
(15) Previously filed as an Exhibit to the registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2018, and incorporated by reference herein.
(16) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2015, and incorporated by reference herein.
(17) Previously filed as an Exhibit to the registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2016, and incorporated by reference herein.
(18) Previously filed as an Exhibit to the registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2018, and incorporated by reference herein.
(19) Previously filed as an Exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-221368), filed with the Securities and Exchange Commission on November 6, 2017, and incorporated by reference herein.
(20) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2017, and incorporated by reference herein.
(21) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 30, 2018, and incorporated by reference herein.
(22) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 13, 2018, and incorporated by reference herein.
(23) Previously filed as an Exhibit to the registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2018, and incorporated by reference herein.
(24) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 24, 2018, and incorporated by reference herein.
(25) Previously filed as an Exhibit to the registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2019, and incorporated by reference herein.
(26) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2019, and incorporated by reference herein.
(27) Previously filed as an Exhibit to the registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2019, and incorporated by reference herein.
(28) Previously filed as an Exhibit to the registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 5, 2019, and incorporated by reference herein.
(29) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 24, 2020, and incorporated by reference herein.
(30) Previously filed as an Exhibit to the registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 13, 2020, and incorporated by reference herein.
(31) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 26, 2021, and incorporated by reference herein.
(32) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 14, 2022, and incorporated by reference herein.

**ITEM 16. FORM 10-K SUMMARY**

None.

**AVINGER, INC.**
**INDEX TO FINANCIAL STATEMENTS**
**As of December 31, 2021 and 2020, and for the**
**Years Ended December 31, 2021 and 2020**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of
Avinger, Inc.

***Opinion on the Financial Statements***

We have audited the accompanying balance sheets of Avinger, Inc. (the "Company") as of December 31, 2021 and 2020, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes and the financial statement schedules (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

***Basis for Opinion***

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

***Critical Audit Matter***

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Valuation of Inventories*

As described in Notes 2 and 4 to the financial statements, the Company's inventories balance was $4.6 million as of December 31, 2021. The Company values its inventories at lower of cost (determined using the first-in, first-out method) or net realizable value. The Company writes down inventory that has expired or become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on the estimates of future demand for a particular product. Changes in assumptions of product demand could have a significant impact on the amount of write-down recorded. The evaluation by management includes analysis of historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions, as well as the feasibility of reworking or using excess or obsolete products or components in the production or assembly of other products that are not obsolete or for which there are not excess quantities in inventory.

We identified the valuation of inventories, in particular the estimates for excess quantities and obsolescence, as a critical audit matter, because of the significant assumptions and subjective judgments used by management, which in turn led to the use of subjective auditor judgment and audit effort to address the matter.

The primary procedures we performed to address the critical audit matter included:

- Evaluating management's process for developing the estimates of excess and obsolete inventories by:
  - Evaluating the methodology utilized to calculate the write-downs;
  - Performing inquiries with management as to the composition of the reserve for inventory items without recent sales;
  - Assessing the appropriateness of the formulaic calculation and management adjustments by product type; and
  - Testing the mathematical accuracy of the formulaic calculation.
- Evaluating the reasonableness of the significant assumptions used by management including those related to future demand by:
  - Evaluating management's ability to provide reasonable forecast of sales by comparing prior period sales forecasts to actual results; and
  - Performing inquiries with nonfinancial personnel, including sales and production employees, regarding obsolete or discontinued inventory items and other factors to corroborate management's assertions regarding qualitative judgments about excess and obsolete inventories or unrecorded reserves.
- Testing the completeness, accuracy, and relevance of the underlying data used in management's estimate and calculations related to the application of the methodology to specific inventory categories by agreement to supporting documentation and recalculation.
- Performing a substantive analytical procedure, whereby we developed an independent expectation of the excess and obsolescence reserve based primarily on historical trends, and compared that expectation to the recorded amount.

/s/ Moss Adams LLP

San Francisco, California
March 22, 2022

We have served as the Company's auditor since 2017.

**AVINGER, INC.**
**BALANCE SHEETS**
***(In thousands, except share and per share data)***

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 19,497 | $ 22,185 |
| Accounts receivable, net of allowance for doubtful accounts of $6 and $19 at December 31, 2021 and 2020, respectively | 1,393 | 1,484 |
| Inventories | 4,601 | 3,876 |
| Prepaid expenses and other current assets | 300 | 350 |
| Total current assets | 25,791 | 27,895 |
| | | |
| Right of use asset | 3,179 | 4,063 |
| Property and equipment, net | 95 | 727 |
| Other assets | 420 | 510 |
| Total assets | $ 29,485 | $ 33,195 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,394 | $ 694 |
| Accrued compensation | 1,609 | 1,703 |
| Accrued expenses and other current liabilities | 718 | 669 |
| Leasehold liability, current portion | 985 | 806 |
| Borrowings, current portion | — | 3,590 |
| Total current liabilities | 4,706 | 7,462 |
| | | |
| Borrowings, long-term portion | 12,287 | 9,400 |
| Leasehold liability, long-term portion | 2,194 | 3,257 |
| Other long-term liabilities | 575 | — |
| Total liabilities | 19,762 | 20,119 |
| | | |
| Commitments and contingencies (Note 9) | | |
| | | |
| Stockholders' equity: | | |
| Convertible preferred stock issuable in series, par value of $0.001 | | |
| Shares authorized: 5,000,000 at December 31, 2021 and 2020 | | |
| Shares issued and outstanding: 56,451 and 52,369 at December 31, 2021 and 2020, respectively; aggregate liquidation preference related to Series A convertible preferred stock of $56,366 and $52,191 at December 31, 2021 and 2020, respectively | — | — |
| Common stock, par value of $0.001 | | |
| Shares authorized: 100,000,000 at December 31, 2021 and 2020 | | |
| Shares issued and outstanding: 4,778,263 and 4,246,308 at December 31, 2021 and 2020, respectively | 96 | 85 |
| Additional paid-in capital | 394,380 | 380,332 |
| Accumulated deficit | (384,753) | (367,341) |
| Total stockholders' equity | 9,723 | 13,076 |
| Total liabilities and stockholders' equity | $ 29,485 | $ 33,195 |

All share and per share data reflect the impact of the reverse stock split effective March 14, 2022. See accompanying notes.

**AVINGER, INC.**
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
***(In thousands, except per share data)***

| | Year Ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Revenues | $ 10,130 | $ 8,761 |
| Cost of revenues | 6,706 | 6,143 |
| Gross profit | 3,424 | 2,618 |
| | | |
| Operating expenses: | | |
| Research and development | 5,900 | 5,695 |
| Selling, general and administrative | 15,625 | 14,327 |
| Total operating expenses | 21,525 | 20,022 |
| Loss from operations | (18,101) | (17,404) |
| | | |
| Interest income | 3 | 34 |
| Interest expense | (1,651) | (1,692) |
| Other income, net | 2,337 | 56 |
| Net loss and comprehensive loss | (17,412) | (19,006) |
| Accretion of preferred stock dividends | (4,175) | (3,866) |
| Net loss applicable to common stockholders | $ (21,587) | $ (22,872) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (4.57) | $ (9.29) |
| | | |
| Weighted average common shares used to compute net loss per share, basic and diluted | 4,722 | 2,462 |

All share and per share data reflect the impact of the reverse stock split effective March 14, 2022. See accompanying notes.

**AVINGER, INC.**
**STATEMENTS OF STOCKHOLDERS' EQUITY**
***(In thousands, except share data)***

| | Convertible Preferred Stock | | Common Stock | | | | Total |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Additional Paid-In Capital | Accumulated Deficit | Stockholders' Equity |
| **Balance at December 31, 2019** | **48,503** | **$ —** | **518,233** | **$ 10** | **$ 355,220** | **$ (348,335)** | **$ 6,895** |
| Issuance of common stock in public offerings, net of commissions and issuance costs | — | — | 3,707,016 | 74 | 23,572 | — | 23,646 |
| Employee stock-based compensation | — | — | — | — | 1,513 | — | 1,513 |
| Issuance of common stock under officers and directors purchase plan and vesting of restricted stock units | — | — | 21,059 | 1 | 27 | — | 28 |
| Issuance of Series A preferred stock to pay dividends | 3,866 | — | — | — | 3,866 | — | 3,866 |
| Accretion of Series A preferred stock dividends | — | — | — | — | (3,866) | — | (3,866) |
| Net and comprehensive loss | — | — | — | — | — | (19,006) | (19,006) |
| **Balance at December 31, 2020** | **52,369** | **—** | **4,246,308** | **85** | **380,332** | **(367,341)** | **13,076** |
| Issuance of common stock in public offerings, net of commissions and issuance costs | — | — | 500,000 | 10 | 13,033 | — | 13,043 |
| Conversion of Series B preferred stock into common stock | (93) | — | 18,600 | — | — | — | — |
| Issuance of common stock upon vesting of restricted stock units | — | — | 13,355 | 1 | — | — | 1 |
| Employee stock-based compensation | — | — | — | — | 1,015 | — | 1,015 |
| Issuance of Series A preferred stock to pay dividends | 4,175 | — | — | — | 4,175 | — | 4,175 |
| Accretion of Series A preferred stock dividends | — | — | — | — | (4,175) | — | (4,175) |
| Net and comprehensive loss | — | — | — | — | — | (17,412) | (17,412) |
| **Balance at December 31, 2021** | **56,451** | **$ —** | **4,778,263** | **$ 96** | **$ 394,380** | **$ (384,753)** | **$ 9,723** |

All share and per share data reflect the impact of the reverse stock split effective March 14, 2022. See accompanying notes.

**AVINGER, INC.**
**STATEMENTS OF CASH FLOWS**
***(In thousands)***

| | Year Ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Cash flows from operating activities** | | |
| Net loss | $ (17,412) | $ (19,006) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 687 | 897 |
| Amortization of debt issuance costs and debt discount | 86 | 168 |
| Stock-based compensation | 1,015 | 1,513 |
| Noncash interest expense and other charges | 1,564 | 1,524 |
| Change in right of use asset | 133 | 169 |
| Provision for excess and obsolete inventories | 125 | 528 |
| Gain on extinguishment of debt | (2,353) | — |
| Other non-cash charges | 2 | (54) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 89 | (1) |
| Inventories | (849) | (490) |
| Prepaid expenses and other current assets | 50 | (48) |
| Other assets | (43) | 5 |
| Accounts payable | 679 | 31 |
| Accrued compensation | (94) | (79) |
| Accrued expenses and other current liabilities | 49 | 15 |
| Other long-term liabilities | 575 | (7) |
| Net cash used in operating activities | (15,697) | (14,835) |
| | | |
| **Cash flows from investing activities** | | |
| Purchase of property and equipment | (34) | — |
| Proceeds from sale of property and equipment | — | 65 |
| Net cash provided by (used in) investing activities | (34) | 65 |
| | | |
| **Cash flows from financing activities** | | |
| Proceeds from the issuance of common stock in public offerings, net of commissions and issuance costs | 13,043 | 23,646 |
| Proceeds from borrowings, net of issuance costs | — | 2,330 |
| Proceeds from issuance of common stock under officers' and directors' purchase plan | — | 36 |
| Net cash provided by financing activities | 13,043 | 26,012 |
| | | |
| Net change in cash and cash equivalents | (2,688) | 11,242 |
| Cash and cash equivalents, beginning of period | 22,185 | 10,943 |
| Cash and cash equivalents, end of period | $ 19,497 | $ 22,185 |
| | | |
| **Supplemental disclosure of cash flow information** | | |
| | | |
| Noncash investing and financing activities: | | |
| | | |
| Accretion of Series A preferred stock dividends | $ 4,175 | $ 3,866 |
| Issuance of Series A preferred stock as dividend payment | $ 4,175 | $ 3,866 |
| Reclassification of right of use asset to prepaid rent | $ (133) | $ (169) |
| Purchases of property and equipment in accounts payable | $ 21 | $ — |

See accompanying notes.

## 1. Organization

### Organization, Nature of Business

Avinger, Inc. (the "Company"), a Delaware corporation, was incorporated in March 2007. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease ("PAD"). Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. The Company manufactures and sells a suite of products in the United States ("U.S.") and in select international markets. The Company has developed its Lumivascular platform, which integrates optical coherence tomography ( "OCT") visualization with interventional catheters and is the industry's only system that provides real-time intravascular imaging during the treatment portion of PAD procedures. The Company's Lumivascular platform consists of a capital component, our Lightbox consoles, as well as a variety of disposable catheter products. The Company's current catheter products includes its Lumivascular platform products, Ocelot and Tigereye, all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ("CTO"). The Company also has image-guided atherectomy solutions under its suite of Lumivascular products, Pantheris and Pantheris SV, which are designed to allow physicians to precisely remove arterial plaque in PAD patients. The Company is located in Redwood City, California.

### Liquidity Matters

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of December 31, 2021, the Company had an accumulated deficit of $384.8 million. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $19.5 million at December 31, 2021, together with approximately $6.7 million net proceeds from the January 2022 equity financing, and expected revenues and funds from operations will be sufficient to allow the Company to fund its current operations through the second quarter of 2023. The Company received net proceeds of approximately $3.9 million from the sale of its common stock in its January 2020 offering, $2.3 million of loan proceeds in April 2020 pursuant to the Paycheck Protection Program ("PPP") under the Coronavirus Aid, Relief and Economic Security ("CARES") Act, which was forgiven in April 2021, $3.0 million from the sale of its common stock in April and May 2020, $5.5 million from the sale of its common stock in June and July 2020, $11.3 million from the sale of its common stock in August and September 2020, and approximately $13.0 million from the sale of its common stock in February 2021. The Company does not have any immediate plans to raise additional funds through future equity or debt financings. However, the Company may decide to raise additional funds to meet its operational needs and capital requirements for product development, clinical trials and commercialization or other strategic objectives.

The Company can provide no assurance that it will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for its existing stockholders. Given the volatility in the Company's stock price, any financing that we may undertake in the next twelve months could cause substantial dilution to its existing stockholders, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its various endeavors. In addition, the COVID-19 pandemic and responses thereto have resulted in reduced consumer and investor confidence, instability in the credit and financial markets, volatile corporate profits, restrictions on elective medical procedures, and reduced business and consumer spending, which could increase the cost of capital and/or limit the availability of capital to the Company. During the second quarter of 2020, the Company took certain actions to manage available cash and other resources to mitigate the effects of COVID-19 on its business, which included reduction of discretionary costs, reduction of base salaries for all of its non-manufacturing employees by 20% and reduction of hours worked by its manufacturing workers by 20%. Salaries and hours worked largely returned to prior levels by July 2020.

On September 22, 2021, we received a letter from Nasdaq's Listing Qualifications Department notifying us that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price for our listed securities was less than $1 for the previous 30 consecutive business days. We had a period of 180 calendar days, or until March 21, 2022, to regain compliance with the rule referred to in this paragraph. To regain compliance, the bid price of our common stock must close at $1 or more for a minimum of ten consecutive business days. The notice has no present impact on the listing of our securities on Nasdaq. On March 14, 2022, we effected a 1-for-20 reverse stock split of our outstanding shares of common stock. However, there is no guarantee that such reverse stock split will result in the bid price of our common stock closing at $1 or more for the required ten consecutive business days.

The Company has not yet regained compliance with the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company provided written notice to Nasdaq requesting an additional 180 calendar days to cure the deficiency on March 17, 2022, but have not yet received a response. If Nasdaq delists our common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we could face significant material adverse consequences including among other things, a decreased ability to issue additional securities or obtain additional financing in the future, a limited availability of market quotations for our securities, reduced liquidity for our securities.

If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding.

**Public Offerings**

On January 31, 2020, the Company completed a public offering of 321,429 shares of common stock at an offering price of $14.00 per share. As a result, the Company received net proceeds of approximately $3.9 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in the February 2018 offering, was reduced to $14.00 per share.

On April 30, 2020, the Company completed a public offering of 630,000 shares of common stock at an offering price of $5.00 per share. On May 6, 2020, the Company issued an additional 94,500 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, the Company received aggregate net proceeds of approximately $3.0 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in the February 2018 offering, was reduced to $5.00 per share.

On June 26, 2020, the Company completed a public offering of 1,000,000 shares of common stock at an offering price of $5.40 per share. On July 9, 2020, the Company issued an additional 150,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering resulting in $0.7 million of additional net proceeds. As a result, the Company received aggregate net proceeds of approximately $5.5 million including the overallotment option and after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 6, 2020, under the universal shelf registration statement filed on March 7, 2019 (the "Shelf Registration Statement,"), the Company completed a public offering of 789,474 shares of common stock at an offering price of $7.60 per share. On August 11, 2020, the Company issued an additional 118,421 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, the Company received aggregate net proceeds of approximately $6.2 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 25, 2020, under the Shelf Registration Statement, the Company completed a public offering of 553,192 shares of common stock at an offering price of $9.40 per share. On September 1, 2020, the Company issued an additional 50,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, the Company received aggregate net proceeds of approximately $5.1 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On February 2, 2021, under the Shelf Registration Statement, the Company completed a bought deal offering of 500,000 shares of common stock at an offering price of $28.80 per share. As a result, the Company received aggregate net proceeds of approximately $13.0 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

*January 2022 Offering*

On January 14, 2022, the Company entered into a securities purchase agreement with several institutional investors pursuant to which the Company agreed to sell and issue, in a registered direct offering ( "January 2022 offering"), an aggregate of 7,600 shares of the Company's Series D Convertible Preferred Stock, par value of $0.001 per share, at an offering price of $1,000 per share. Concurrently, the Company agreed to issue to these investors warrants to purchase up to an aggregate of 807,500 shares of the Company's common stock (the "Common Warrants"). As a result, the Company received aggregate net proceeds of approximately $6.7 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

In connection with the January 2022 offering and in accordance with the securities purchase agreement, the Company held a special meeting of stockholders on March 11, 2022 to consider a proposal (the "Proposal") to amend to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Charter") to effect a reverse split of the outstanding shares of the Company's common stock at a ratio between 1-for-5 and 1-for-20 (the "Reverse Split Amendment"). The Company's stockholders approved the Reverse Split Amendment at the special meeting. On March 11, 2022, following receipt of stockholder approval, the Company's Board of Directors approved a reverse split ratio of 1-for-20 and the Company filed an amendment to our Charter to effect such reverse stock split, effective as of 5:00 pm Eastern Time on March 14, 2022.

Pursuant to the purchase agreement, the Company filed a certificate of designation (the "Certificate of Designation") with the Secretary of State of Delaware designating the rights, preferences and limitations of the shares of Series D preferred stock, which became effective on January 14, 2022. The Certificate of Designation provided, in particular, that the Series D preferred stock will have no voting rights, other than the right to vote as a class on certain matters, except that each share of Series D preferred stock had the right to cast 37,500 votes per share of Series D preferred stock on the Proposal (the "Supermajority Voting Rights"); provided, that the votes cast by the holders of the Series D preferred stock must be counted in the same proportion as the aggregate shares of common stock voted on the Proposal. Because the Proposal was approved by our stockholders at the special meeting held on March 11, 2022, the Series D preferred stock no longer has Supermajority Voting Rights.

The holders of the Series D preferred stock are entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Series D preferred stock is convertible into shares of common stock at a conversion price of $8.00 per share, as adjusted for the most recent reverse stock split. The conversion price can be adjusted pursuant to the Certificate of Designation for stock dividends and stock splits, subsequent rights offerings, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the Certificate of Designation). The Series D preferred stock can be converted at the option of the holders at any time. In addition, subject to the satisfaction of certain conditions, the Company may cause the holders of the Series D preferred stock to convert their shares of Series D preferred stock; provided, that shares of Series D preferred stock cannot be converted to common stock if the applicable holder would beneficially own in excess of 4.99% (or, upon election by such holder prior to the issuance of any shares of Series D preferred stock, 9.99%) of our outstanding common stock. A holder of Series D preferred stock may, upon notice to the Company, increase or decrease such beneficial ownership limitation, but not in excess of 9.99%.

The Common Warrants have an exercise price of $9.60 per share and become exercisable beginning July 14, 2022. The Common Warrants will expire five years following the time they become exercisable, or July 14, 2027. The Company also issued to the Placement Agent or its designees warrants to purchase up to an aggregate of 66,500 shares of common stock (the "Placement Agent Warrants"). The Placement Agent Warrants are subject to the same terms as the Common Warrants, except that the Placement Agent Warrants have an exercise price of $10.00 per share and a term of five years from the commencement of the sales pursuant to the January 2022 Offering, or January 12, 2027.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

On March 11, 2022, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-20 reverse stock split of the Company's issued and outstanding common stock. The reverse stock split became effective on March 14, 2022. The par value of the common stock and preferred stock was not adjusted as a result of the reverse stock split. All common stock, stock options, restricted stock units, and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its stock-based compensation, accruals related to compensation, the valuation of the common stock warrants, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

**Fair Value of Financial Instruments**

The Company has evaluated the estimated fair value of its financial instruments as of December 31, 2021 and 2020. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities and borrowings. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of the borrowings approximate their fair value.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. As of December 31, 2021 and 2020, the Company's cash equivalents are entirely comprised of investments in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity. There were no unrealized gains and losses as of December 31, 2021 and 2020. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

**Concentration of Credit Risk, and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable to the extent of the amounts recorded on the balance sheets.

The Company's policy is to invest in cash and cash equivalents, consisting of money market funds. These financial instruments are held in Company accounts at one financial institution. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing. The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at December 31, 2021 and 2020.

The Company's accounts receivable are due from a variety of healthcare organizations in the United States and select international markets. At December 31, 2021 and 2020, there was one customer that represented 21% and 14% of accounts receivable. For the year ended December 31, 2021, there was one customer that represented 10% of revenues. For the year ended December 31, 2020, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

The Company manufactures its commercial products in-house, including the Pantheris and Ocelot family of catheters. Certain of the Company's product components and sub-assemblies are manufactured by sole suppliers, including internally. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

The Company is subject to certain risks, including that its devices may not be approved or cleared for marketing by governmental authorities or be successfully marketed. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon third-party payors to provide adequate coverage and reimbursement, dependence on key personnel and suppliers, protection of proprietary technology, product liability claims, and compliance with government regulations.

Existing or future devices developed by the Company may require approvals or clearances from the FDA or international regulatory agencies. In addition, in order to continue the Company's operations, compliance with various federal and state laws is required. If the Company were denied or delayed in receiving such approvals or clearances, it may be necessary to adjust operations to align with the Company's currently approved portfolio. If clearance for the products in the current portfolio were withdrawn by the FDA, this may have a material adverse impact on the Company.

Disruption of our supply chain capabilities due to trade restrictions, political instability, severe weather, natural disasters, public health crises such as the ongoing COVID-19 pandemic, terrorism, product recalls, labor supply or stoppages, the financial or operational instability of key suppliers and carriers, government restrictions or measures, or other reasons could impair our ability to distribute our products. Many industries, including our own, face supply chain challenges as a result of COVID-19 and other macroeconomic issues, including reduced freight availability and increased costs, port disruption, manufacturing facility closures, labor shortages and other supply chain disruptions. To the extent we are unable to mitigate the likelihood or potential impact of such events, there could be a material adverse effect on our operating and financial results.

**Accounts Receivable**

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company determines the allowance for doubtful accounts based upon an aging of accounts receivable, historical experience, and management judgment. Accounts receivable balances are reviewed individually for collectability. To date, the Company has not experienced significant credit-related losses.

Accounts receivable allowance for doubtful accounts provision and recoveries or write-offs are summarized as follows (in thousands):

| | 2021 | 2020 |
|---|---|---|
| Beginning balance | $ 19 | $ 19 |
| Provision | 2 | 26 |
| Recoveries/write-offs | (15) | (26) |
| Ending balance | $ 6 | $ 19 |

**Inventories**

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has expired or become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. At each balance sheet date, management evaluates inventories for excess quantities, and obsolescence. This evaluation by management includes analysis of historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions, as well as the feasibility of reworking or using excess or obsolete products or components in the production or assembly of other products that are not obsolete or for which there are not excess quantities in inventory. To the extent that management determines there are excess or obsolete inventory, management adjusts the carrying value to estimated net realizable value. When quantities on hand exceed sales forecasts, a write-down is recorded for such excess inventories along with a corresponding charge to cost of revenues. The estimate of excess quantities is subjective and primarily dependent on the estimates of future demand for a particular product. Changes in assumptions of product demand could have a significant impact on the amount of write-down recorded. Inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. The cost of inventories are regularly reviewed against estimated market value and record a lower of cost or market reserve for inventories that have a cost in excess of estimated market value, which could have a material impact on the gross margin and inventory balances based on additional write-downs to net realizable value or a benefit from inventories previously written down.

**Property and Equipment**

Property and equipment are recorded at cost. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets of generally three to five years. Depreciation expense includes the amortization of assets acquired under capital leases and equipment located at customer sites. Equipment held by customers is comprised of the Lightbox consoles located at customer sites under a lease or placement agreement. Upon execution of a lease or placement agreement, the related equipment is reclassified from inventory to the property and equipment account. Depreciation expense for equipment held by customers is recorded as a component of cost of revenues. Leasehold improvements and assets recorded under capital leases are amortized using the straight-line method over the shorter of the lease term or estimated useful economic life of the asset.

**Impairment of Long-Lived Assets**

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of the long-lived asset exceeds its fair value. The Company has not recorded any impairment of long-lived assets since inception through December 31, 2021.

**Revenue Recognition**

The Company's revenues are derived from (1) sale of Lightbox consoles, (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts and maintenance. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. The Company's revenues are measured based on consideration specified in the contract with each customer, net of any sales incentives and taxes collected from customers that are remitted to government authorities. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement. The Company's revenue recognition policies generally result in revenue recognition at the following points:

1. Lightbox console sales: Provided all other criteria for revenue recognition have been met, the Company recognizes revenue for Lightbox console sales directly to end customers when delivery and acceptance occurs, which is defined as receipt by the Company of an executed form that the installation process is complete.

2. Sales of disposables: Disposable revenues consist of sales of the Company's catheters and accessories and are recognized when the product has shipped, risk of loss and title has passed to the customer and collectability is reasonably assured.

3. Service revenue: Service contract revenue consists of preventative maintenance, upgrades, and service contracts. Service contracts are recognized ratably over the term of the service period and maintenance contract revenue is recognized as work is performed. To date, service revenue has been insignificant.

The Company offers its customers the ability to purchase or lease the Lightbox console. In addition, the Company provides a Lightbox under a limited commercial evaluation program to allow accounts to install and utilize the Lightbox for a limited trial period. When a Lightbox is placed under a lease agreement or under a commercial evaluation program, the Company retains title to the equipment and it remains capitalized on its balance sheet under property and equipment. Depreciation expense on these placed Lightboxes is recorded to cost of revenues on a straight-line basis. The costs to maintain these placed Lightboxes are charged to cost of revenues as incurred.

The Company evaluates its lease and commercial evaluation program agreements and accounts for these contracts under the guidance in Accounting Standards Codification ("ASC") 842, *Leases* and ASU No. 2014 09, *Revenue from Contracts with Customers (Topic 606)*. The guidance requires arrangement consideration to be allocated between a lease deliverable and a non-lease deliverable based upon the relative selling-price of the deliverables.

The Company assessed whether the embedded lease is an operating lease or sales-type lease. Based on the Company's assessment of the guidance and given that any payments under the lease agreements are dependent upon contingent future sales, it was determined that collectability of the minimum lease payments is not reasonably predictable. Accordingly, the Company concluded the embedded lease did not meet the criteria of a sales-type lease and accounts for it as an operating lease. The Company recognizes revenue allocated to the lease as the contingent disposable product purchases are delivered and are included in revenues within the statement of operations and comprehensive loss.

For sales through distributors, the Company recognizes revenue when control of the product transfers from the Company to the distributor. The distributors are responsible for all marketing, sales, training and warranty in their respective territories. The standard terms and conditions contained in the Company's distribution agreements do not provide price protection or stock rotation rights to any of its distributors. In addition, its distributor agreements do not allow the distributor to return or exchange products, and the distributor is obligated to pay the Company upon invoice regardless of its ability to resell the product.

**Cost of Revenues**

Cost of revenues consists primarily of manufacturing overhead costs, material costs and direct labor. A significant portion of the Company's cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of revenues also includes depreciation expense for the Lightboxes under lease and evaluation agreements, product warranty costs, product written-off due to excess or obsolescence, and certain direct costs such as shipping costs.

**Product Warranty Costs**

The Company typically offers a one-year warranty on its products commencing upon the transfer of title and risk of loss to the customer. The Company accrues for the estimated cost of product warranties upon invoicing its customers, based on historical results. Warranty costs are reflected in the statement of operations and comprehensive loss as a cost of revenues. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. Periodically the Company assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. Warranty provisions and claims are summarized as follows (in thousands):

| | 2021 | 2020 |
|---|---|---|
| Beginning balance | $ 193 | $ 215 |
| Warranty provision | 49 | 142 |
| Usage/Release | (55) | (164) |
| Ending balance | $ 187 | $ 193 |

**Research and Development**

The Company expenses research and development costs as incurred. Research and development expenses include personnel and personnel-related costs, costs associated with pre-clinical and clinical development activities, and costs for prototype products that are manufactured prior to market approval for that prototype product, and internal and external costs associated with the Company's regulatory compliance, including the costs of outside consultants and contractors that assist in the process of submitting and maintaining regulatory filings, and overhead costs, including allocated facility and related expenses.

**Clinical Trials**

The Company accrues and expenses costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company determines these estimates through discussion with internal personnel and outside service providers as to progress or stage of completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services.

**Stock-Based Compensation**

Stock-based compensation for the Company includes amortization related to all stock options, restricted stock units ("RSU"), based on the grant-date estimated fair value. The fair value of stock options is estimated on the date of grant using the Black-Scholes option pricing model and recognized as expense on a straight-line basis over the vesting period of the award. The Company has not granted any stock options since 2017. The Company measures the fair value of RSUs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. As allowed under ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, the Company accounts for forfeitures as they occur.

**Foreign Currency**

The Company records net gains and losses resulting from foreign exchange transactions as a component of foreign currency exchange losses in other income, net. During the years ended December 31, 2021 and 2020, the Company recorded $16,000 and $18,000 of foreign currency exchange net (gains)/losses, respectively.

**Income Taxes**

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense when they occur. During the years ended December 31, 2021 and 2020, the Company did not recognize accrued interest or penalties related to unrecognized tax benefits.

**Net Loss per Share Attributable to Common Stockholders**

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholder by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders' continued service to the Company. As of December 31, 2021 and 2020, there were no shares subject to repurchase. Since the Company was in a loss position for both periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

Net loss per share attributable to common stockholders was determined as follows (in thousands, except per share data):

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Net loss applicable to common stockholders | $ (21,587) | $ (22,872) |
| Weighted average common stock outstanding, basic and diluted | 4,722 | 2,462 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (4.57) | $ (9.29) |

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an anti-dilutive impact due to losses reported:

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Common stock warrants equivalents | 135,430 | 137,700 |
| Common stock options | 335 | 351 |
| Convertible preferred stock | 52,289 | 48,503 |
| Unvested restricted stock units | 17,793 | 35,971 |
| | 205,847 | 222,525 |

**Comprehensive Loss**

For the years ended December 31, 2021 and 2020, there was no difference between comprehensive loss and the Company's net loss.

**Segment and Geographical Information**

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets, which are comprised of property and equipment, are based in the United States. For each of the years ended December 31, 2021 and 2020, 94% of the Company's revenues were in the United States, based on the shipping location of the external customer.

**Recent Accounting Pronouncements**

*Recently adopted accounting standards*

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which among other things, eliminates certain exceptions in the current rules regarding the approach for intraperiod tax allocations and the methodology for calculating income taxes in an interim period, and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard was adopted by the Company on January 1, 2021. The adoption of this new standard did not have a material impact on the Company's financial statements.

*Recent accounting standards not yet adopted*

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which among other things, simplifies the accounting models for the allocation of proceeds attributable to the issuance of a convertible debt instrument. As a result, after adopting the ASU's guidance, entities will not separately present in equity an embedded conversion feature in such debt. Instead, they will account for a convertible debt instrument wholly as debt, and for convertible preferred stock wholly as preferred stock (i.e., as a single unit of account), unless (i) a convertible instrument contains features that require bifurcation as a derivative under ASC 815 or (ii) a convertible debt instrument was issued at a substantial premium. The standard becomes effective for the Company in the first quarter of 2024 and early adoption is permitted. This new standard is not expected to have a material impact on the Company's financial statements.

In May 2021, ASU No. 2021-04, *Issuer's Accounting for Certain Modifications of Exchanges of Freestanding Equity-Classified Written Call Options* was issued to clarify the accounting for modifications or exchanges of freestanding equity-classified written call options, such was warrants, that remain equity classified after modification or exchange. This ASU became effective for the Company on January 1, 2022 and is not expected to have a material impact on the financial statements.

**3. Fair Value Measurements**

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than quoted prices included within Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2021 and 2020, the Company's cash equivalents were all categorized as Level 1 and consisted of money market funds. As of December 31, 2021 and 2020, there were no financial assets and liabilities categorized as Level 2 or Level 3. There were no transfers between fair value hierarchy levels during the years ended December 31, 2021 and 2020.

In January 2022, the Company issued warrants to purchase common stock categorized as Level 3.

**4. Inventories**

Inventories consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Raw materials | $ 2,503 | $ 1,904 |
| Work-in-process | 1 | 180 |
| Finished products | 2,097 | 1,792 |
| Total inventories | $ 4,601 | $ 3,876 |

**5. Property and Equipment, Net**

Property and equipment, net, consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Equipment held by customers | $ 2,362 | $ 2,746 |
| Machinery and equipment | 1,391 | 1,679 |
| Computer software | 122 | 122 |
| Computer equipment | 173 | 144 |
| Furniture and fixture | 78 | 78 |
| Leasehold improvements | 320 | 311 |
| Total property and equipment, gross | 4,446 | 5,080 |
| Less: Accumulated depreciation and amortization | (4,351) | (4,353) |
| Total property and equipment, net | $ 95 | $ 727 |

Depreciation expense for the years ended December 31, 2021 and 2020, was approximately $687,000 and $897,000, respectively.

Property and equipment include certain equipment that is leased to customers and located at customer premises. The Company retains the ownership of the equipment held for evaluation and has the right to remove the equipment if it is not being utilized according to expectations. Depreciation expense relating to the leased equipment held by customers of $539,000 and $629,000 was recorded in cost of revenues during the years ended December 31, 2021 and 2020, respectively. This leased equipment was fully depreciated as of December 31, 2021. The net book value of this leased equipment was $518,000 at December 31, 2020.

**6. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Accrued product warranty costs | $ 187 | $ 193 |
| Accrued clinical trial costs | 153 | 96 |
| Deferred revenue | 123 | 28 |
| Accrued travel expenses | 118 | 104 |
| Accrued sales and use tax | 33 | 43 |
| Accrued professional fees | — | 65 |
| Other accrued liabilities | 104 | 140 |
| Total accrued expenses and other current liabilities | $ 718 | $ 669 |

**7. Borrowings**

*CRG*

On September 22, 2015, the Company entered into a Term Loan Agreement, as amended (the “Loan Agreement”) with CRG under which, subject to certain conditions, the Company had the right to borrow up to $50 million in principal amount from CRG on or before March 29, 2017. The Company borrowed $30 million on September 22, 2015. The Company borrowed an additional $10 million on June 15, 2016 under the Loan Agreement.

On February 14, 2018, the Company and CRG further amended the Loan Agreement concurrent with the conversion of $38 million of the principal amount of the senior secured term loan (plus $3.8 million in back-end fees and prepayment premium applicable thereto) into a newly authorized Series A convertible preferred stock (see below).

On March 2, 2020, the Company entered into Amendment No. 3 to the Loan Agreement to, among other things:

- extend the period that the Company can make interest payments in payment in kind ("PIK") to June 30, 2021;
- lower the Minimum Revenue Covenants to $10 million for 2020, $12 million for 2021, and $15 million for 2022;
- insert certain terms to clarify that all fees, including the prepayment premium, are due if the obligations are accelerated; and
- insert a new provision to make clear that to the extent the Company divides its assets/liabilities into divisions, such assets/liabilities will be treated as transferred to a third party.

On May 12, 2020, the Company entered into Amendment No. 4 to the Loan Agreement to, among other things:

- grant to the Company the right to optionally prepay in whole or in part the outstanding principal amount of the Loans for the Redemption Price, subject to certain conditions; and
- waive the Company's requirement to comply with the Minimum Revenue Covenant for 2020.

On January 22, 2021, the Company entered into Amendment No. 5 to the Loan Agreement to, among other things:

- extend the maturity date of the Loan Agreement from June 30, 2023 to December 31, 2025;
- extend the interest only payment period and the period that the Company can make interest payments in PIK to December 31, 2023;
- lower the Minimum Revenue Covenants to $8 million and $10 million for 2021 and 2022, respectively and establish revenue covenants of $12 million for 2023; $14.5 million for 2024, and $17 million for 2025;
- change the date under the on-going stand-alone representation regarding no Material Adverse Change to December 31, 2020;
- and amend the on-going stand-alone representation and stand-alone event of default regarding "Material Adverse Change" such that any adverse change in or effect upon the revenue of the Company and its subsidiaries due to the outbreak of COVID-19 will not constitute a Material Adverse Change

Under the amended Loan Agreement, no cash payments for either principal or interest are due until the first quarter of 2024. The interest will be accrued and included in the debt balance based (to the extent not paid) on principal amounts outstanding at the beginning of the quarter at an interest rate of 12.5%. Beginning in the first quarter of 2024, the Company will be required to make quarterly principal payments (in addition to the interest) of $1.9 million with total principal payments of $7.5 million in 2024 and $7.5 million in 2025. The maturity date of the Loan is December 31, 2025.

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after seven and half years of the loan. Each tranche of borrowing required the payment, on the borrowing date, of a financing fee equal to 1.5% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 15.0% of the amounts borrowed plus any payment-in-kind ("PIK") is to be payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The borrowings are collateralized by a security interest in substantially all of the Company's assets.

The Loan Agreement requires that the Company adheres to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the amended Loan Agreement included a covenant that the Company maintain a minimum of $3.5 million of cash and certain cash equivalents, and the Company has to achieve certain minimum revenues. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company with a cure right if it prepays a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company's capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change.

As of December 31, 2021, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of December 31, 2021, principal, final facility fee and PIK payments under the Loan Agreement, which incorporates all amendments occurring prior to our fiscal year end, were as follows (in thousands):

| **Year Ending December 31,** | |
|---|---|
| 2022 | $ — |
| 2023 | — |
| 2024 | 9,045 |
| 2025 | 10,339 |
| Total | 19,384 |
| Less: Amount of PIK additions and final facility fee to be incurred subsequent to December 31, 2021 | (6,765) |
| Less: Amount representing debt issuance costs | (332) |
| Borrowings, long term portion, as of December 31, 2021 | $ 12,287 |

In connection with drawdowns under the Loan Agreement, the Company recorded aggregate debt discounts of $1.3 million as contra-debt. The debt discounts are being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of December 31, 2021 and 2020, the balance of the aggregate debt discount was approximately $333,000 and $418,000, respectively. The Company's interest expense associated with the amortization of debt discount was approximately $86,000 and $169,000 during the years ended December 31, 2021 and 2020, respectively. The Company incurred total interest expense of approximately $1.6 million and $1.5 million during the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, all of the CRG borrowings and associated aggregate debt discount were classified as non-current.

*Paycheck Protection Program*

On April 23, 2020, the Company received loan proceeds of $2.3 million (the "PPP Loan") pursuant to the PPP under the CARES Act.

The Loan, which was in the form of a promissory note, dated April 20, 2020 (the "Promissory Note"), between the Company and Silicon Valley Bank ("SVB") as the lender, was set to mature on April 20, 2022 and bore interest at a fixed rate of 1% per annum, payable monthly commencing six months from the date of the Loan. The Company may voluntarily prepay the borrowings in full with no associated penalty or premium.

The PPP was administered by the U.S. Small Business Administration (the "SBA"). The SBA was given the authority under the PPP to forgive loans if all employees were kept on the payroll for a required period and the loan proceeds were used for payroll, rent and utilities. The Company applied for debt forgiveness in December 2020.

On April 17, 2021, the Company was notified by SVB that its PPP Loan had been fully forgiven by the SBA and that there was no remaining balance on the PPP Loan. The Company recorded the forgiveness as other income in April 2021 in the amount of $2.4 million, of which approximately $23,000 was accrued interest.

For the years ended December 31, 2021 and 2020, the Company incurred interest expense of approximately $7,000 and $16,000, respectively, related to the PPP Loan.

**8. Leases**

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments.

The lease will expire on November 30, 2024. The Company is obligated to pay approximately $5.8 million in base rent payments through November 2024, beginning on December 1, 2019. The weighted average remaining lease term as of December 31, 2021 is 2.9 years.

The operating lease was included on the balance sheet at the present value of the future base payments discounted at a 6.5% discount rate using the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment as the lease does provide an implicit rate.

The Company's operating lease expense, excluding variable maintenance fees and other expenses on a monthly basis, was approximately $105,000. Rent expense for both the years ended December 31, 2021 and 2020 was approximately $1.3 million. Our variable expenses for both the years ended December 31, 2021 and 2020 was approximately $0.2 million. Operating right-of-use asset amortization for the year ended December 31, 2021 and 2020 was approximately $1.0 million and $964,000, respectively. Due to payments being made in excess of operating lease expense recognized, the Company recorded approximately $158,000 and $291,000 as prepaid rent included in other assets on the balance sheet as of December 31, 2021 and 2020, respectively.

The following table presents the future operating lease payments and leasehold liability included on the balance sheet related to the Company's operating lease as of December 31, 2021 (in thousands):

| **Year Ending December 31,** | |
|---|---|
| 2022 | $ 1,162 |
| 2023 | 1,203 |
| 2024 | 1,138 |
| Total | 3,503 |
| Less: Imputed interest | (324) |
| Leasehold liability as of December 31, 2021 | $ 3,179 |

The following table shows ROU assets and lease liabilities, and the associated financial statement line items, as of December 31, 2021 and December 31, 2020 (in thousands):

| **Lease-Related Assets and Liabilities** | **Financial Statement Line Items** | **December 31, 2021** | **December 31, 2020** |
|---|---|---|---|
| Right of use assets: | | | |
| Operating lease | Right of use asset | $ 3,179 | $ 4,063 |
| Total right of use assets | | $ 3,179 | $ 4,063 |
| Lease liabilities: | | | |
| Operating lease | Leasehold liability, current portion | $ 985 | $ 806 |
| | Leasehold liability, long-term portion | 2,194 | 3,257 |
| Total lease liabilities | | $ 3,179 | $ 4,063 |

**9. Commitments and Contingencies**

**Purchase Obligations**

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancelable commitments to suppliers for purchases totaling approximately $1.4 million as of December 31, 2021. The majority of this amount is related to commitments to purchase inventory components for our various product lines.

**Indemnification**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future, but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations for any period presented.

**Legal Proceedings**

The Company is not currently involved in any pending legal proceedings that it believes could have a material adverse effect on our financial condition, results of operations or cash flows. From time to time, the Company may be involved in legal proceedings or investigations, which could harm our reputation, business and financial condition and divert the attention of our management from the operation of our business.

**10. Stockholders' Equity**

**Convertible Preferred Stock**

As of December 31, 2021, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of convertible preferred stock with $0.001 par value per share, of which 56,451 shares were issued and outstanding. As of December 31, 2020, there were 52,369 shares of convertible preferred stock issued and outstanding.

*Series A Convertible Preferred Stock*

The holders of Series A preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at the Company's option. The shares of Series A preferred stock have a liquidation preference of $1,000 per share, no voting rights and rank senior to all other classes and series of the Company's equity in terms of repayment and certain other rights. During the years ended December 31, 2021 and 2020, 4,175 and 3,866 additional shares, respectively, were issued to CRG as payment of dividends. As of December 31, 2021, 56,366 shares of Series A preferred stock were outstanding, which are currently convertible into shares of the Company's common stock at $400 per share. The Series A preferred stock annual dividends of approximately $4.2 million and $3.9 million during the years ended December 31, 2021 and 2020, respectively.

*Series B Convertible Preferred Stock*

The Series B preferred stock has a liquidation preference of $0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. During the year ended December 31, 2021, 93 of these shares converted into 18,600 shares of common stock. As of December 31, 2021, 85 shares of Series B preferred stock remained outstanding, which are currently convertible into shares of the Company's common stock at $5 per share.

*Series D Convertible Preferred Stock*

On January 14, 2022, the Company entered into a security purchase agreement with several institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering ( "January 2022 offering"), an aggregate of 7,600 shares of the Company's Series D convertible preferred stock, par value $0.001 per share at an offering price of $1,000 per share. Concurrently, the Company agreed to issue to these investors warrants to purchase up to an aggregate of 807,500 shares of the Company's common stock (the "Common Warrants"). The shares of Series D Preferred Stock has a stated value of $1,000 per share and are convertible into an aggregate of 950,000 shares of common stock at a conversion price of $8.00 per share.

The Series D preferred stock has no voting rights, other than the right to vote as a class on certain matters, except that each share of Series D preferred stock has the right to cast 37,500 votes per share of Series D preferred stock on a one-time proposal (the "Proposal") to amend to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Charter") to effect a reverse split of the outstanding shares of the Company's common stock at a ratio between 1-for-5 and 1-for-20 (the "Reverse Split Amendment") (the "Supermajority Voting Rights"); provided, that the votes cast by the holders of the Series D preferred stock must be counted by the Company in the same proportion as the aggregate shares of common stock voted on the Proposal. Because the Proposal was approved by our stockholders at the special meeting held on March 11, 2022, the Series D preferred stock no longer has Supermajority Voting Rights.

The holders of the Series D preferred stock are entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Series D preferred stock is convertible into shares of common stock at a conversion price of $8.00 per share, as adjusted for the most recent reverse stock split. The conversion price can be adjusted pursuant to the Certificate of Designation for stock dividends and stock splits, subsequent rights offerings, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the Certificate of Designation). The Series D preferred stock can be converted at the option of the holders at any time. In addition, subject to the satisfaction of certain conditions, we may cause the holders of the Series D preferred stock to convert their shares of Series D preferred stock; provided, that shares of Series D preferred stock cannot be converted to common stock if the applicable holder would beneficially own in excess of 4.99% (or, upon election by such holder prior to the issuance of any shares of Series D preferred stock, 9.99%) of our outstanding common stock. A holder of Series D preferred stock may, upon notice to us, increase or decrease such beneficial ownership limitation, but not in excess of 9.99%.

**Common Stock**

At December 31, 2021, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 4,778,263 shares were issued and outstanding.

**Common Stock Warrants**

As of December 31, 2021, we had outstanding warrants to purchase common stock as follows, which include the warrants issued in connection with the Company's January 2022 offering:

| | Total Outstanding and Exercisable | Underlying Shares of Common Stock | Exercise Price per Share | Expiration Date |
|---|---|---|---|---|
| Series 1 Warrants issued in the February 2018 Series B financing | 8,979,000 | 44,895 | $ 400.00 | February 2025 |
| Series 2 Warrants issued in the February 2018 Series B financing | 8,709,500 | 43,548 | $ 400.00 | February 2025 |
| Warrants issued in the November 2018 financing | 8,768,395 | 43,842 | $ 80.00 | November 2023 |
| Placement agent warrants issued in the January 2022 financing | 1,330,000 | 66,500 | $ 10.00 | January 2027 |
| Warrants issued in the January 2022 financing | 16,150,000 | 807,500 | $ 9.60 | September 2027 |
| Total | 43,936,895 | 1,006,285 | | |

As of December 31, 2020, we had outstanding warrants to purchase common stock as follows:

| | Total Outstanding and Exercisable | Underlying Shares of Common Stock | Exercise Price per Share | Expiration Date |
|---|---|---|---|---|
| Series 1 Warrants issued in the February 2018 Series B financing | 8,979,000 | 44,895 | $ 400.00 | February 2025 |
| Series 2 Warrants issued in the February 2018 Series B financing | 8,709,500 | 43,548 | $ 400.00 | February 2025 |
| Warrants issued in the July 2018 financing | 1,083,091 | 5,416 | $ 316.00 | July 2021 |
| Warrants issued in the November 2018 financing | 8,768,395 | 43,842 | $ 80.00 | November 2023 |
| Total | 27,539,986 | 137,701 | | |

Pursuant to the purchase agreement entered into on January 14, 2022, the Company issued the Common Warrants to purchase up to an aggregate of 807,500 shares of the Company's common stock at an exercise price of $9.60 per share and become exercisable beginning July 14, 2022. The Common Warrants will expire five years following the time they become exercisable, or July 14, 2027. The exercise price and the number of shares of common stock issuable upon exercise of each common warrant is subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. In addition, in certain circumstances, upon a fundamental transaction, a holder of Common Warrants will be entitled to receive, upon exercise, the kind and amount of securities, cash or other property that such holder would have received had they exercised the Common Warrants immediately prior to the fundamental transaction.

The Common Warrants can be exercised at the option of the holders at any time after they become exercisable provided that shares of the Common Warrants cannot be exercised into common stock if the applicable holder would beneficially own in excess of 4.99% (or, upon election by such holder prior to the issuance of any shares of Common Warrants, 9.99%) of the Company's outstanding common stock immediately after giving effect to the exercise. A holder of the Common Warrants may, upon notice to the Company, increase or decrease such beneficial ownership limitation, but not in excess of 9.99%.

The Company also issued to the placement agent of the January 2022 Offering warrants to purchase up to an aggregate of 66,500 shares of common stock (the "Placement Agent Warrants"). The Placement Agent Warrants are subject to the same terms as the Common Warrants, except that the Placement Agent Warrants have an exercise price of $10.00 per share and a term of five years from the commencement of the sales pursuant to the January 2022 Offering, or January 12, 2027.

During the year ended December 31, 2021, a total of 1,083,091 warrant shares to purchase a total of up to 5,416 shares of common stock that issued in connection with the July 2018 financing expired without being exercised. As of December 31, 2021 and 2020, warrants to purchase an aggregate of 1,006,285 and 137,701 shares of common stock, respectively, were outstanding.

**Stock Plans**

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Equity Incentive Plan ("2015 Plan"). The 2015 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of non-statutory stock options ("NSOs"), restricted stock, restricted stock units ("RSUs"), stock appreciation rights, performance units and performance shares to employees, directors and consultants. The shares reserved for issuance under the 2015 Plan includes share awards granted under the prior equity incentive plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2015 Plan includes an automatic annual increase on the first day of each fiscal year equal to the lesser of 211 shares, 5.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year or an amount as determined by the Board of Directors. As of December 31, 2021, 8,480 shares were available for grant under the 2015 Plan.

Pursuant to the 2015 Plan, ISOs and NSOs may be granted with exercise prices at not less than 100% of the fair value of the common stock on the date of grant and the exercise price of ISOs granted to a stockholder, who, at the time of grant, owns stock representing more than 10% of the voting power of all classes of the stock of the Company, shall be not less than 110% of the fair market value per share of common stock on the date of grant. The Company's Board of Directors determines the vesting schedule of the options. Options granted generally vest over four years and expire ten years from the date of grant.

Stock option activity under the Plans is set forth below:

| | Number of Shares (in thousands) | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Balance at December 31, 2019 | 370 | $ 26,189.40 | | $ — |
| Options expired | (28) | $ 42,583.40 | | |
| Options forfeited | (1) | $ 16,400.00 | | |
| Balance at December 31, 2020 | 341 | $ 24,831.70 | 5.81 | $ — |
| Options expired | (10) | $ 58,632.36 | | |
| Options forfeited | — | $ — | | |
| Balance at December 31, 2021 | 331 | $ 23,815.95 | 4.93 | $ — |
| | | | | |
| Exercisable at December 31, 2021 | 331 | $ 23,815.95 | 4.93 | $ — |
| | | | | |
| Vested and expected to vest at December 31, 2021 | 331 | $ 23,815.95 | 4.93 | $ — |

Additional information related to the Company's stock options as of December 31, 2021 is summarized as follows:

| Options Outstanding | | | | Options Vested | |
|---|---|---|---|---|---|
| Exercise Price | Options Outstanding | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $ 334.00 | 155 | 6.44 | $ 334.00 | 155 | $ 334.00 |
| $ 400.00 - 29,400.00 | 39 | 5.18 | $ 17,372.31 | 39 | $ 17,372.31 |
| $ 36,000.00 | 110 | 3.00 | $ 36,000.00 | 110 | $ 36,000.00 |
| $ 87,280.00 - 162,000.00 | 27 | 3.69 | $ 115,913.85 | 27 | $ 115,913.85 |
| | 331 | 4.93 | $ 23,342.58 | 331 | $ 23,342.58 |

There were no options granted or exercised during either of the years ended December 31, 2021 or 2020. For the years ended December 31, 2021 and 2020, stock-based compensation expense recognized associated with stock options vesting was approximately $4,000 and $58,000, respectively. As of December 31, 2021, there is no remaining unamortized stock-based compensation expense associated with unvested stock options. Because of the Company's net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the years ended December 31, 2021 and 2020.

The Company's RSUs generally vest annually over three years in equal increments. The Company measures the fair value of RSUs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. A summary of all RSU activity is presented below:

| | Number of Shares | Weighted Average Grant Date Fair Value | Weighted Average Remaining Contractual Term |
|---|---|---|---|
| Awards outstanding at December 31, 2019 | 45,425 | $ 81.80 | 1.81 |
| Awarded | 2,375 | $ 11.60 | |
| Released | (18,407) | $ 91.40 | |
| Forfeited | (8,761) | $ 54.40 | |
| Awards outstanding at December 31, 2020 | 20,632 | $ 76.82 | 0.98 |
| Awarded | 4,500 | $ 32.20 | |
| Released | (13,355) | $ 104.23 | |
| Forfeited | (1,727) | $ 53.79 | |
| Awards outstanding at December 31, 2021 | 10,050 | $ 24.37 | 0.72 |

As of December 31, 2021, there was approximately $0.2 million of remaining unamortized stock-based compensation expense associated with RSUs, which will be expensed over a weighted average remaining service period of less than one year. The outstanding non-vested and expected to vest RSUs at December 31, 2021 have an aggregate fair value of approximately $0.1 million. The Company used the closing market price of $9 per share at December 31, 2021 to determine the aggregate fair value for the RSUs outstanding at that date. For the years ended December 31, 2021 and 2020, the fair value of RSUs vested was approximately $273,000 and $135,000, respectively. For the years ended December 31, 2021 and 2020, stock-based compensation expense recognized associated with the vesting of RSUs was approximately $1.0 million and $1.5 million, respectively.

**2018 Officer and Director Share Purchase Plan**

On August 22, 2018, the Board of Directors of the Company approved the adoption of an Officer and Director Share Purchase Plan ("ODPP"), which allows executive officers and directors to purchase shares of our common stock at fair market value in lieu of salary or, in the case of directors, director fees. Eligible individuals may voluntarily participate in the ODPP by authorizing payroll deductions or, in the case of directors, deductions from director fees for the purpose of purchasing common stock. The Board of Directors authorized 1,000 shares to be made available for purchase by officers and directors under the ODPP. Effective on August 28, 2019 and March 10, 2020, the Board of Directors approved an additional 2,000 and 6,250 shares, respectively, to be made available under the ODPP. There was no common stock issued under the ODPP during the year ended December 31, 2021. Common stock issued under the ODPP during the year ended December 31, 2020 totaled 2,652 shares. As of December 31, 2021, there were 4,609 shares reserved for issuance under the ODPP.

**11. Stock-Based Compensation**

Total noncash stock-based compensation expense relating to the Company's stock options and RSUs recognized, before taxes, during the years ended December 31, 2021 and 2020, is as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Cost of revenues | $ 101 | $ 132 |
| Research and development expenses | 287 | 469 |
| Selling, general and administrative expenses | 627 | 912 |
| | $ 1,015 | $ 1,513 |

**12. Income Taxes**

For the years ended December 31, 2021 and 2020, the Company's provision for income taxes consisted of zero state income tax expense. A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Tax at federal statutory rate | $ (3,657) | $ (3,991) |
| State taxes, net of federal benefit | (711) | (760) |
| Permanent differences | (445) | 56 |
| Change in valuation allowance | 5,104 | 4,909 |
| Research credits | (286) | (211) |
| Other | (5) | (3) |
| Provision for taxes | $ — | $ — |

Significant components of the Company's net deferred tax assets as of December 31, 2021 and 2020 consist of the following (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Deferred tax assets: | | |
| Federal, state and foreign net operating losses | $ 83,211 | $ 79,253 |
| Research and other credits | 4,892 | 4,766 |
| Operating lease liability | 752 | 994 |
| Accruals and other | 2,845 | 2,305 |
| Total deferred tax assets | 91,700 | 87,318 |
| Less: Valuation allowance | (90,908) | (86,193) |
| Total net deferred tax assets | 792 | 1,125 |
| Deferred liabilities: | | |
| Fixed assets | (2) | (60) |
| Operating lease right of use asset | (790) | (1,065) |
| Total deferred tax liabilities | (792) | (1,125) |
| Net deferred tax assets (liabilities) | $ — | $ — |

The valuation allowance increased by $4.7 million and increased by $3.4 million during the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, the Company had approximately $334.4 million of federal and $204.8 million of state net operating loss carryforwards available to offset future taxable income. If not utilized, the federal and state net operating loss carryforwards begin to expire in 2027 and 2024, respectively. Out of the Federal net operating loss carryforwards, $76.9 million were generated post December 31, 2017 and have no expiration.

As of December 31, 2021, the Company also had approximately $3.9 million of research and development tax credit carryforwards available to reduce future taxable income, if any, for both federal and California purposes. The federal credit carryforwards expire beginning in 2027, and the California research credits do not expire and may be carried forward indefinitely.

The Company's ability to utilize the net operating loss and tax credit carryforwards in the future may be subject to substantial restrictions in the event of past or future ownership changes as defined in Section 382 of the Internal Revenue Code and similar state tax laws. In the event the Company should experience an ownership change, as defined, utilization of the Company's net operating loss carryforwards and tax credits could be limited.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information.

A reconciliation of the beginning and ending amount of the gross recognized tax benefit is as follows (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Balance at beginning of year | $ 2,307 | $ 2,094 |
| Increase based on the tax positions in the current year | 228 | 169 |
| (Decrease) Increase for tax positions of prior year | (169) | 44 |
| Balance at end of year | $ 2,366 | $ 2,307 |

As of December 31, 2021, all unrecognized tax benefits would be subject to a full valuation allowance, if recognized, and would not affect the Company's tax rate.

The Company does not anticipate that the total amounts of unrecognized tax benefits will significantly increase or decrease in the next twelve months.

The Company's policy is to include interest and penalties related to unrecognized tax benefits within its provision for income taxes. Due to the Company's net operating loss position, the Company has not recorded an accrual for interest or penalties related to uncertain tax positions for the years ended December 31, 2021 or 2020.

The Consolidated Appropriations Act, 2021 (the "Act") was enacted in the United States on December 27, 2020. The Act enhances and expands certain provisions of the CARES Act, which among other things, allows deductions for expenses paid with proceeds from the PPP Loan.

**13. 401(k) Plan**

The Company has a qualified retirement plan under section 401(k) of the Internal Revenue Code ("IRC") under which participants may contribute up to 99% of their eligible compensation, subject to maximum deferral limits specified by the IRC. The Company may make a discretionary matching contribution to the 401(k) plan, and may make a discretionary employer contribution to each eligible employee each year. To date, the Company has made no contributions to the 401(k) plan.

**14. Subsequent Events**

On March 15, 2022, certain holders of Series D preferred stock opted to convert their Series D preferred stock into common stock. A total of 5,200 shares of Series D preferred stock were converted resulting in the issuance of an aggregate of 650,000 shares of common stock. After giving effect to these aforementioned conversions, there remains 2,400 shares of Series D preferred stock, which if converted, would result in the issuance of 300,000 shares of common stock.

## SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

**Avinger, Inc.**
(Registrant)

Date: March 22, 2022

/s/ Jeffrey M. Soinski
Jeffrey M. Soinski
*Chief Executive Officer*
*(Principal Executive Officer)*

Date: March 22, 2022

/s/ Mark Weinswig
Mark Weinswig
*Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Soinski and Mark Weinswig, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Jeffrey M. Soinski<br>Jeffrey M. Soinski | President and Chief Executive Officer (Principal Executive Officer);<br>Director | March 22, 2022 |
| /s/ Mark Weinswig<br>Mark Weinswig | Chief Financial Officer (Principal Financial and Accounting Officer) | March 22, 2022 |
| /s/ James B. McElwee<br>James B. McElwee | Director | March 22, 2022 |
| /s/ James G. Cullen<br>James G. Cullen | Director | March 22, 2022 |
| /s/ Tamara Elias<br>Tamara Elias | Director | March 22, 2022 |

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-222517, 333-227308, and 333-227689), Form S-3 (No. 333-230124) and Form S-8 (Nos. 333-201928, 333-209364, 333-216695, 333-227072, 333-233498, and 333-237046) of Avinger, Inc. (the "Company"), of our report dated March 22, 2022, relating to the financial statements and schedules of the Company, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2021.

/s/ Moss Adams LLP

San Francisco, California
March 22, 2022

**Exhibit 31.1**

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER**
**Pursuant to**
**Securities Exchange Act Rules 13a-14(a) and 15d-14(a),**
**As Adopted Pursuant to**
**Section 302 of the Sarbanes-Oxley Act of 2002**

I, Jeffrey Soinski, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report on Form 10-K, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report on Form 10-K based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 22, 2022

/s/ Jeffrey M. Soinski
Jeffrey M. Soinski
*Chief Executive Officer*
*(Principal Executive Officer)*

**Exhibit 31.2**

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER**
**Pursuant to**
**Securities Exchange Act Rules 13a-14(a) and 15d-14(a),**
**As Adopted Pursuant to**
**Section 302 of the Sarbanes-Oxley Act of 2002**

I, Mark Weinswig, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 22, 2022

/s/ Mark Weinswig
Mark Weinswig
*Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

**Exhibit 32.1**

**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER**
**AND CHIEF FINANCIAL OFFICER**
**PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Avinger, Inc. (the "Company") on Form 10-K for the period ended December 31, 2021, as filed with the Securities and Exchange Commission (the "Report"), Jeffrey Soinski, as Chief Executive Officer of the Company, and Mark Weinswig, Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 22nd day of March, 2022.

| | |
|---|---|
| /s/ Jeffrey M. Soinski | /s/ Mark Weinswig |
| Jeffrey M. Soinski | Mark Weinswig |
| *Chief Executive Officer* | *Chief Financial Officer* |
| *(Principal Executive Officer)* | *(Principal Financial and Accounting Officer)* |

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.